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RECEIVED
MAY 30 2007
RICHARD W. WIEKING
CLERK, U.S. DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

COYNESS L. ENNIX, JR., M.D., as an individual and in his representative capacity under Business & Professions Code Section 17200 et seq.,

Plaintiff,

v.

RUSSELL D. STANTEN, M.D., LEIGH I.G. IVERSON, M.D., STEVEN A. STANTEN, M.D., WILLIAM M. ISENBERG, M.D., Ph.D., ALTA BATES SUMMIT MEDICAL CENTER and does 1 through 100,

Defendants.

CASE NO. C 07-2486 WHA

DECLARATION OF LAMONT D. PAXTON, M.D. IN SUPPORT OF DEFENDANTS' SPECIAL MOTION TO STRIKE COMPLAINT UNDER C.C.P. 425.16

DATE: July 5, 2007
TIME: 8:00 a.m.
DEPT: Ctrm. 9, 19th Flr.
JUDGE: Hon. William H. Alsup

COMPLAINT FILED: May 9, 2007
TRIAL DATE: No date set

I, Lamont D. Paxton, M.D., declare as follows:

1. I am a member of the Medical Staff of Alta Bates Summit Medical Center, Summit Campus ("ABSMC-Summit), specializing in vascular surgery.

2. In about July 2004, I was asked by William Isenberg, M.D., then President of the Medical Staff, to serve on and chair an Ad Hoc Committee ("AHC") for the purpose of investigating the practice of Coyness Ennix, M.D. The other members of the AHC were Dat Ly, M.D., an anesthesiologist, and Barry Horn, M.D., a pulmonologist/intensivist. Dr. Isenberg informed me that he had notified Dr. Ennix of the AHC's appointment.

3. In a letter to Dr. Ennix dated August 24, 2004, I confirmed the appointment of the AHC, and noted that the investigation would cover his performance of minimally invasive procedures, as well as other matters involving his practice, more generally, both at the Summit Campus and the Alta Bates Campus of ABSMC. I assured him that no conclusions would be drawn on any substantial issues without first giving him an opportunity to comment. I stated that our intent was to complete our task as soon as possible, but that our top priority was to be fair and complete. The AHC was committed to these principles, and we adhered to them throughout the investigation.

4. The AHC met nineteen (19) times. We interviewed the Chair of the Department of Surgery, the Chief of the Cardiovascular Surgery Service, two other cardiac surgeons, three anesthesiologists, one staff member, and finally Dr. Ennix. At and between meetings, we reviewed available documentation regarding Dr. Ennix's performance at the Alta Bates and Summit Campuses, Cardiothoracic Peer Review Committee activities regarding Dr. Ennix's performance at the Summit Campus, the medical records for all or most of the cases in which substantial issues had been raised, statistical data on morbidity and mortality, and other relevant documentation, including correspondence from the Medical Staff leadership. We also engaged the services of National Medical Audit ("NMA"), a reputable independent peer review organization, to

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assist us in reviewing ten (10) specific cases that appeared clearly to involve substantial quality of care issues.

5. During the course of the AHC's investigation, Dr. Ennix was kept abreast of developments, informed of the issues presented, and allowed to submit materials for NMA's consideration. Before NMA prepared its findings, arrangements were made for Dr. Ennix to have extensive telephone conferences with the two independent practitioners who were assigned by NMA to review the cases. One was a cardiothoracic surgeon in San Diego, and the other was a cardiovascular surgeon in Chicago. In a letter to Dr. Isenberg dated April 5, 2005, Dr. Ennix expressed his gratitude for the opportunity to speak with the reviewers and address the issues.

6. NMA submitted its Report on May 3, 2005, expressing serious concerns about Dr. Ennix's judgment, technique and documentation. Dr. Ennix was given a copy of the Report. Dr. Ennix then attacked the competence and motives of the NMA reviewers. He described them as "business men," suggesting that they were commercially motivated to find fault with his practice. He also produced voluminous documentation referring to legal controversies in which the reviewers had been involved over the years. We investigated the issues, and found no reasonable justification for disregarding or discounting the reviewers' findings. Some of the issues raised by Dr. Ennix had no relevance to the reviewers' professional practices; and the malpractice cases that were listed by Dr. Ennix, without revealing the results, had all been resolved in favor of the reviewers or, in a few instances, settled for small amounts.

7. The AHC proceeded to consider the NMA Report, along with other information collected during the investigation, and invited Dr. Ennix to meet with us prior to the preparation of our final conclusions. We had three (3) meetings with Dr. Ennix, each of which lasted approximately two (2) hours. He commented not only on each of the cases discussed in the NMA Report, but also on the peer review information received from the Alta Bates Campus; the statistical data comparing his mortality rates with those of his partners and other cardiac surgeons nationally; a recent case that,

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combined with the NMA Report, resulted in the summary suspension of his privileges by the President of the Medical Staff on May 10, 2005; other information about which he was asked to comment; and the fairness and objectivity of the peer review process. He submitted several binders of materials, including articles and statistical data, for reference during our discussion. Following our meetings with Dr. Ennix, the AHC met again on three (3) occasions, for a total of approximately six (6) hours, to review his presentation and conduct our deliberations. We then prepared our own Report and Recommendation to the Medical Executive Committee ("MEC"), dated August 1, 2005.

8. A true and correct copy of the AHC's Report and Recommendation is attached to this Declaration as Exhibit A, including Appendix A, which is a complete copy of the NMA Report, and Appendix B, which is a comparative study of Dr. Ennix's mortality data from January 1, 1999 through April 30, 2005.

9. On August 1, 2005, the President of the Medical Staff sent Dr. Ennix a copy of the AHC's Report and Recommendation, and invited him to attend a special meeting of the MEC on August 15, 2005, to discuss it. Dr. Ennix was also given the opportunity to supplement his presentation with written materials, if he wished. I was invited to attend as Chair of the AHC. Dr. Ennix appeared at the meeting and requested a three-week postponement of his discussion with the MEC, which was granted. He then left the meeting. I remained to answer questions about the AHC's Report and Recommendation.

10. On September 7, 2005, Dr. Ennix met with the MEC to discuss the AHC's Report and Recommendation. He submitted a considerable amount of new information that had not been made available to the AHC. I was present for the discussion. Subsequently, an agreement was reached between Dr. Ennix and the MEC that involved certain restrictions of his clinical privileges, including proctoring requirements and monitoring functions. The AHC was to participate in the monitoring functions at six-month intervals, pending a determination by the MEC that monitoring was no longer necessary.

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11. I have continued to serve as an available resource to the MEC for purposes of reviewing noteworthy cases or issues that have arisen in Dr. Ennix's practice. For example, in late December, 2005, and early January, 2006, I worked with Steven Stanten, M.D., Chair of the Department of Surgery, to review a series of ten (10) cases, five (5) of which involved complications as noted by Dr. Ennix's proctors. As a result of those cases, Dr. Stanten and Dr. Isenberg had decided to summarily suspend Dr. Ennix's clinical privileges on December 10, 2005, pending further review. After we reviewed those cases in detail, we determined that the suspension should be lifted, and it was.

12. On May 4, 2006, the AHC reviewed Dr. Ennix's proctoring reports, and determined that there were an inadequate number of cases to warrant a conclusion that the proctoring requirements should be lifted. On July 10, 2006, after reviewing additional cases, the AHC recommended to the MEC that the proctoring requirements be discontinued. (Dr. Barry Horn resigned from the AHC in April, 2006.) However, the AHC also recommended that 100% retrospective chart review be conducted on an ongoing basis, by the Chief of the Cardiac Surgery Service and/or his designees. The Chief of the Service was, and still is, Russell Stanten, M.D. The MEC adopted these recommendations.

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13. Throughout my involvement in the activities described in this Declaration, I have seen no evidence of "sham peer review" or racial discrimination against Dr. Ennix by any committee or individual. All of the activities with which I am familiar have been conducted solely for purposes of evaluating and improving the quality of patient care at ABSMC-Summit, without the slightest indication of any other motives.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed this 2 day of May, 2007, at Oakland, California.

Lamont D. Paxton

LAMONT PAXTON, M.D.

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EXHIBIT A

CONFIDENTIAL

PRIVILEGED AND CONFIDENTIAL

MEMORANDUM

To: **Medical Executive Committee**

From: **Ad Hoc Committee:**
Lamont D. Paxton, M.D., Chair
Barry Horn, M.D.
Dat Ly, M.D.

Date: **August 1, 2005**

Re: **Coyness L. Ennix, Jr., M.D.; Investigative Report and Recommendation**

I. BACKGROUND

Early in 2004, Coyness L. Ennix, Jr., M.D. performed a series of four minimally invasive valve procedures at the Summit Campus of Alta Bates Summit Medical Center. They were the first procedures of this type to have been performed here, and problems were encountered in all four cases. The cases were reviewed initially by a cardiothoracic surgeon on the Medical Staff, who found significant deficiencies in some of Dr. Ennix's documentation, but expressed the opinion that his clinical performance otherwise met the applicable standard of care. The Surgery Peer Review Committee ("PRC") disagreed, finding that the cases exhibited shortcomings in Dr. Ennix's clinical judgment and/or skills. Dr. Ennix volunteered to refrain from performing any additional minimally invasive valve procedures until the issues could be resolved by an ad hoc committee and the Medical Executive Committee ("MEC"). He subsequently informed the Chair of the Department of Surgery and the President of the Medical Staff that he had decided never to perform these procedures again.

It was noted by the Medical Staff leadership that, at the same time, there were broader concerns regarding Dr. Ennix's practice. For example, on December 18, 2003, John Rosenberg, M.D., M.P.H., President of the Alta Bates Medical Staff, provided a copy of a peer review report by Forrest Junod, M.D., an outside expert, raising issues regarding Dr. Ennix's quality of care before he transferred his practice to the Summit Campus in 2003. In a letter dated March 17, 2004, William Isenberg, M.D., Ph.D., President of the Summit Medical Staff, requested further information. In a letter dated April 15, 2004, Dr. Rosenberg responded in part by referring to Dr. Junod's report as having identified issues regarding "selection for surgery, length of operating time, clinical judgment, time 'on pump,' intra-operative technique and appropriateness of post-operative care." Dr. Rosenberg expressly recommended, on behalf of the responsible peer review panel at Alta Bates, that further review be conducted here.

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In addition, data had been generated through routine Quality Assurance and Cardiothoracic PRC activities at Summit, suggesting possible deficiencies in Dr. Ennix's clinical performance.

On April 13, 2004, the Summit MEC received a report of the information that was available at that time, and authorized Dr. Isenberg to continue his review and, at his discretion, appoint an ad hoc committee to investigate Dr. Ennix's practice. Dr. Ennix was so informed in a letter from Dr. Isenberg dated April 21, 2004.

Dr. Isenberg subsequently appointed this investigative Ad Hoc Committee ("AHC"), comprised of Lamont D. Paxton, M.D., Chair, Barry Horn, M.D., and Dat Ly, M.D. We met for the first time on August 13, 2004. On August 24, 2004, we sent Dr. Ennix a letter informing him of our appointment, and assuring him that we would conduct a fair and complete investigation, which would include an opportunity for him to meet with us and discuss the issues before any conclusions were drawn.

II. OVERVIEW OF INVESTIGATION

The AHC met 19 times. We interviewed the Chair of the Department of Surgery, the Chief of the Cardiovascular Surgery Service, two other cardiac surgeons, three anesthesiologists, one staff member, and finally Dr. Ennix. We reviewed the available documentation regarding Dr. Ennix's performance at Alta Bates, the available documentation regarding Cardiothoracic PRC activities focusing on his practice at Summit, the medical records for all or most of the cases in which substantial issues were raised, statistical data on morbidity and mortality, and other relevant documentation, including correspondence with the Medical Staff leadership.

We determined, based on the results of our initial activities, that we could not reach reliable conclusions without the benefit of input from one or more experts from outside the Medical Staff. Therefore, we engaged National Medical Audit ("NMA"), an independent peer review organization with which the Medical Staff had prior favorable experience, to assist us in reviewing ten specific cases that appeared clearly to involve substantial issues. NMA assigned a cardiothoracic surgeon in private practice in San Diego and a cardiovascular surgeon in private practice in Chicago to review the cases. Cardiologists were also consulted on some issues. Dr. Ennix was kept abreast of developments, informed of the issues presented, and allowed to submit materials for the reviewers' consideration. Arrangements were also made for Dr. Ennix to speak personally with each reviewer in a series of telephone conferences moderated by NMA's physician liaison. NMA submitted its final Report on May 3, 2005. A copy is attached hereto as **Appendix A**.

After we received NMA's Report, we sent a copy to Russell Stanten, M.D., Chief of the Cardiothoracic Surgery Service, and interviewed him regarding NMA's findings (it was Dr. Stanten's third interview with the AHC). We also sent a copy to Dr. Ennix, and reviewed it with him personally over the course of three meetings, each of which lasted approximately two hours. He commented not only on each of the cases reviewed in the NMA Report, but also on the peer review information received from Alta Bates; the statistical data comparing his mortality rates with those of his partners and other cardiac surgeons nationally; the recent case that, combined with the NMA Report, resulted in the summary suspension of his privileges on May 10, 2005;

other information about which he was asked to comment; and the fairness and objectivity of the peer review process. He submitted several binders of materials, including articles and statistical data, for reference during our discussions. Following our meetings with Dr. Ennix, we met again on three occasions, for a total of approximately six hours, to review Dr. Ennix's presentation and conduct our deliberations.

All of the documentation relating to the AHC's activities is available for review in the Medical Staff Office.

Having conducted what we believe to have been a fair and comprehensive investigation, we respectfully submit this Report and Recommendation.

III. DETAILS OF INVESTIGATION

A. Cases Reviewed by NMA

(1) Minimally Invasive Valve Procedures

The four cases that involved minimally invasive valve procedures were (by hospital medical record number / NMA's case review number): MR #120506 / ABS-001; MR #1282678 / ABS-002; MR #1282803 / ABS-003; and MR #1283240 / ABS-004. All of these patients were admitted between January 28, 2004 and February 5, 2004.

As noted above, these were the first cases of their kind to be performed here, and they did not go well. This is not open to serious dispute, even by the cardiac surgeon who reviewed the cases initially and faulted Dr. Ennix only for deficient documentation. In his view, which was shared by Dr. Ennix, the clinical problems were primarily attributable to the normal learning curve associated with any new procedure, and not to poor judgment or technique on the part of the surgeon. (The initial reviewer did note, when he met with the AHC, that he was surprised by the valve sizing problems, and he would not have chosen aortic valves to start with. The first three cases were aortic valves.)

The Surgery PRC did not accept the initial reviewer's findings regarding these cases. It concluded, instead, that the complications and problems related to their management could not be explained by the documentation failures alone. The printed summary of the PRC's discussion includes a reference to Dr. Ennix's "record overall," and to concerns, generally, regarding his "patient selection, technical skills and judgment skills, particularly when cases are not going well." The anesthesiologists and surgeons interviewed by the AHC who were familiar with these cases all voiced similar concerns, and uniformly opposed Dr. Ennix performing minimally invasive valve procedures in the future. The NMA Report supports the concerns expressed by Dr. Ennix's colleagues.

On April 26, 2004, Dr. Ennix voluntarily restricted his surgical privileges to eliminate minimally invasive valve procedures. Although he vacillated on this shortly afterward, he has since reaffirmed that he does not intend ever to perform such procedures again. Under the circumstances, we do not see a need to discuss these cases in great detail, but there are certain

issues relating to them that have broader implications and therefore warrant attention in this report. For example (this is not an exhaustive list of the issues):

(a) Poor documentation.

Everyone, including Dr. Ennix, agrees that his documentation was poor.

The patient consent process was not documented in any detail, despite the fact that this was a new procedure at this facility and involved special risks. In response to the concerns that were expressed about this, Dr. Ennix obtained letters from patients and/or their families stating that he had explained the procedures to them and obtained their informed consents pre-operatively. These letters cannot substitute for adequate and contemporaneous documentation in the medical record. They are also of questionable reliability, at best, having been prepared a year after the fact, with help from Dr. Ennix in the context of this investigation.

Dr. Ennix's operative notes were also seriously deficient, failing to include essential information such as a description of the patient's valve or condition that the operation was being performed to address, blood usage, operative time (even when substantially prolonged), difficulties encountered during the procedure, intra-operative decisions (including changes of plans), and other major events. With one exception, they were all dictated late (up to four days post-op), and none of the transcriptions was signed less than 94 days post-op (ABS-004 was still not signed as of the date of NMA's review, 300 days post-op). In one case (ABS-001), there were numerous transcription errors, calling into question whether the transcription had been reviewed before it was signed.

Other documentation deficiencies correctly pointed out by NMA included a progress note on post-op day one stating that the patient was doing well, when in fact she was in respiratory failure (ABS-002).

(b) Errors in judgment.

These cases involved substantial errors in judgment by Dr. Ennix.

One patient (ABS-001) was a severe schizophrenic who was likely incapable of understanding the issues associated with this new procedure, even if they had been explained to him. No pre-operative psychiatric consultation was obtained for purposes of establishing the patient's capacity to give a valid consent. This was the very first patient selected by Dr. Ennix for minimally invasive valve surgery at this facility. When Dr. Ennix discussed the issue with NMA, he reportedly conceded that a pre-operative psychiatric consultation would have been a good idea; however, when he met with the AHC, he insisted that the patient had given informed consent.

The second patient (ABS-002), a 37-year-old female, presented with chest pain and an abnormal ECG, yet Dr. Ennix failed to obtain a cardiac cath as part of his pre-operative evaluation. His echo report was also brief, affecting pre-operative planning on valve size

and root issues. When the AHC met with Dr. Ennix, he argued that a cardiac cath was not indicated, and he cited cases in support of this, but those cases were not comparable.

Another problem in the second case (ABS-002) was that Dr. Ennix selected a valve that was too small, resulting in complications during the procedure. According to the NMA Report, he explained that this was a small woman, who already had 4-5 children and led a sedentary life, so she would be fine with a valve this size. It was poor judgment, in the AHC's view, for Dr. Ennix to have assumed that this 37-year-old female weighing 135 pounds would never wish to take a hike or engage in more strenuous activity than a #17 valve would accommodate. A second operation may well be required to replace the valve with a larger size.

The fourth patient (ABS-004) did not have a pre-operative treadmill evaluation to document LV function under stress. This would have been instrumental in determining whether the surgery could be safely postponed.

Perhaps the most important judgmental error on Dr. Ennix's part was his failure to assure that the anesthesiologists and the staff were adequately trained and orientated regarding this new procedure before he began scheduling and performing it. In one case (ABS-002), Dr. Ennix told NMA that the prolonged operative time was partly attributable to the anesthesiologist's inexperience in coronary sinus catheterization as necessary for the procedure; in another case (ABS-004), Dr. Ennix attributed the prolonged operative time in part to the inexperience of the team (technicians, nurses, anesthesiologists and perfusionists). It was Dr. Ennix's responsibility to anticipate these problems and take reasonable steps to avoid them.

(c) **Technical errors.**

In one case (ABS-001), Dr. Ennix made technical errors leading to ventricular damage and a perivalvular leak, and a second operation was necessary to correct the problem. While it appears that the complication was attributable to the minimally invasive approach, which will no longer be an issue in Dr. Ennix's practice, the documentation does not show what went wrong or why the problem was not detected and addressed during the initial surgery. Dr. Ennix's comment to the AHC was that other surgeons, too, have problems that sometimes require take-backs. This was not an adequate response.

In another case (ABS-003), following the valve procedure, the patient developed severe aortic insufficiency and did not survive. At post-mortem, it was determined that the valve was damaged. It is unknown whether the valve had a manufacturing defect or was damaged by Dr. Ennix during the procedure. NMA observed that there were likely technical difficulties that were not described in the op note, and that the type of damage described in the pathology report could have occurred from bending or distorting the sewing ring during valve insertion. Dr. Ennix claimed that the valve was manufactured defectively, but he could not give a reasonable explanation for his failure to see the defect upon visual inspection before using it or to detect it and correct the problem. The concern is that Dr. Ennix is not as attentive as he should be to details such as the

condition of a valve before it is implanted and the existence of possible problems requiring attention before completing a procedure.

(2) **CABG Procedures**

NMA was asked to review 6 cases involving CABG procedures after which the patients died: MR #1132816 / ABS-005; MR #1281866 / ABS-006; MR #1296513 / ABS-007; MR #527129 / ABS-008; MR #6533343 / ABS-009; and MR #1124908 / ABS-010.

As noted above, Dr. Ennix's cardiac surgery privileges were summarily suspended on May 10, 2005. On May 18, 2005, the MEC decided, after meeting with Dr. Ennix, to keep the suspension in place pending the results of this investigation. On May 19, 2005, Dr. Ennix and the MEC agreed that, in lieu of the complete suspension of his privileges, Dr. Ennix's privileges would be restricted to surgical assisting, only, pending the outcome of this investigation. Dr. Ennix has made it clear that he is unwilling to accept this restriction voluntarily as a permanent measure, and seeks to resume his practice as a cardiothoracic surgeon with unrestricted privileges at this facility. Given the importance of these cases for purposes of determining whether that would be appropriate, we will discuss them individually. They are presented in chronological order.

(a) **MR #6533343 / ABS-009, admitted January 9, 2002.**

This case occurred two years earlier than most of the cases that were referred to NMA for review. It was cited by one of the anesthesiologists who was interviewed, to illustrate why he feels compelled, generally, to be especially attentive to coagulation management and other safety issues when practicing with Dr. Ennix, even to this day.

In this case, the point was that Dr. Ennix had "insisted" on operating immediately on a patient who was a Jehovah's Witness, without clearly establishing that there was no time to give the patient iron or erythropoetin (EPO). The patient had a hematocrit of 28-30, and the anesthesiologist felt that, unless it was clearly necessary to go forward at that time, the procedure should be delayed. The anesthesiologist did state that Dr. Ennix appears to have learned something from this and another case regarding the management of Jehovah's Witness patients with low hematocrits. He also noted that no "care issues" were identified when this case was subjected to internal peer review.

As noted by NMA, there is no documentation in the medical record supporting Dr. Ennix's contention that the operation had to be performed urgently. However, Dr. Ennix made a reasonable argument, referring to the opinion of the cardiologist and the time it would take for EPO to become effective, that it was an appropriate judgment call for the surgery to go forward. NMA does not appear to fault Dr. Ennix for this, nor do we.

NMA also noted that Dr. Ennix's documentation of the consent process was substandard, but acknowledges that the consent process was probably adequate, based on correspondence from the patient's family.

During the procedure, which began off-pump, it became necessary to convert to on-

pump. NMA expressed concerns about the amount of time this took (approximately 40 minutes), and stated that the prolonged period of ischemia "was at least partially to blame for the patient's subsequent problems" leading to death. Dr. Ennix responded by saying that he waited to convert because, at times, the instability is only transient and will resolve itself if one waits 5-10 minutes. This is not disputed, in the abstract. However, once again, Dr. Ennix's op report is of no help in explaining what happened. In his discussions with NMA and the AHC, he could only speculate on why the conversion took so long.

(b) MR #1281866 / ABS-006, admitted January 16, 2004

The procedure started as an off-pump coronary artery bypass, but after the first distal anastomosis was completed, the patient became unstable and Dr. Ennix converted to on-pump.

The relative risks and benefits of starting off-pump could be argued either way, and NMA does not criticize Dr. Ennix for it in this case. Nor is Dr. Ennix criticized for converting to on-pump, which was necessary at the time.

The only apparent issue regarding the surgery itself, relates to a note by the perfusionist that Dr. Ennix had to re-do one of the bypass grafts and the fact that this was not mentioned by Dr. Ennix in his op note, which was dictated seven days following the procedure. Dr. Ennix was not well-prepared to discuss this issue when he was interviewed by the NMA reviewer, but he subsequently satisfied the AHC, with reference to documentation in the record, that he would not have re-done a bypass graft in this case.

The most logical explanation for the discrepancy in the chart is that Dr. Ennix did not communicate adequately with the perfusionist during the procedure. The AHC does see this as a problem. According to one of the cardiac surgeons interviewed by the AHC, Dr. Ennix "has not been good" at communicating with perfusionists and anesthesiologists.

This case also raises consent issues. Dr. Ennix's typed consultation note does not describe a detailed discussion of the surgical risks, which would have been important in this case. However, he did produce a letter from the patient's family and offer an explanation that, in this instance, appears to have convinced NMA that the consent process was adequate. We do not disagree with that assessment. Dr. Ennix acknowledged that the documentation in the medical record should have been better.

(c) MR #1132816 / ABS-005, admitted February 27, 2004.

NMA's assessment was that this case involved poor judgment in performing an emergency CABG that led to the patient's death. NMA's reasoning is described in detail in its Report. Essentially, it boils down to: (1) the opinion of the referring cardiologist, with which the NMA reviewers (including both a cardiac surgeon and a cardiologist) disagree, that high-risk surgery was the only option reasonably available to this patient; and (2) Dr. Ennix's decision to defer to that opinion instead of declining to perform the

surgery on the grounds that it was not indicated and the patient was unlikely to survive the operation.

Dr. Ennix's response was factually inconsistent on some points regarding his pre-operative evaluation and personal familiarity with the patient's angiogram. The inconsistencies could not be resolved based on facts documented in the medical record. Fundamentally, it appears that Dr. Ennix did not wish to question the judgment of the referring cardiologist, who is well-regarded in his specialty and a valued referral source. There are some problems with that response, but the AHC is not inclined to make a major issue of it with reference to this particular case. The patient was unlikely to live either way, and Dr. Ennix's decision gave her at least some chance of survival, albeit remote. NMA recognized this phenomenon as a systemic issue, noting that our Medical Staff would benefit from the development of a process for additional consultations in cases such as this. We agree, as discussed more fully elsewhere in this report.

Once again, NMA correctly observed that Dr. Ennix's documentation was seriously deficient. Among other things, his op note had numerous transcription errors that appear to have gone unnoticed. The op note was dictated on the day of the operation, but not signed until two months later. The only statement regarding consent was: "The risk, plan and technique have been discussed with the patient and her family." Dr. Ennix conceded that his documentation was not what it should have been.

(d) **MR #527129 / ABS-008, admitted May 6, 2004.**

In this case, the issue is whether it was appropriate for Dr. Ennix to have proceeded with surgery in the presence of an iatrogenic coagulopathy disorder, instead of postponing it for a few hours or questioning the cardiologist's judgment that surgery was the only option. Prior to the procedure, the patient experienced retroperitoneal bleeding, and that, added to the blood loss at the time of surgery, resulted in significant transfusions of blood components. She subsequently developed multi-organ failure and died on the sixth day post-op.

The cardiologist, a respected member of the Medical Staff, submitted a letter stating that catheter-based intervention was not an option due to the complexity of the affected vessels, and that he referred the patient to Dr. Ennix for "urgent CABG." His letter further states that he discussed the situation thoroughly with Dr. Ennix, and they "agreed CABG was the best approach, even with the known retroperitoneal hematoma."

NMA's view is that the surgery was contraindicated at the time it was performed, and that safer options were available, including waiting for the Integrilin to wear off or taking a non-surgical approach. The NMA reviewer expressed the opinion that the lesion was not overly complex, and that "90% of interventionalists would have proceeded with a PCI of the RCA" in lieu of surgery.

It is beyond the scope of the AHC's task to evaluate the cardiologist's opinion regarding the availability of a non-surgical option. On the issue of whether Dr. Ennix should have

gone forward with the surgery when he did, it is not clear from the cardiologist's letter that his reference to the need for "urgent" surgery was meant as an endorsement of Dr. Ennix's decision to perform "immediate" surgery, without waiting even a few hours for the Integrilin to wear off. Either way, the AHC agrees with NMA that it is ultimately the surgeon's responsibility to decide whether, and if so when, a procedure should be performed. In this instance, the risks were enormous, as borne out by the results, and it was not good judgment for Dr. Ennix to have performed the surgery when he did.

This patient had complex cardiologic, vascular, and bleeding issues. As noted by NMA, it is impossible to know what was communicated to the patient and/or family regarding the risks and benefits associated with immediate versus delayed surgery or other important issues, because there was no substantial documentation describing the discussion in the medical record. Dr. Ennix's preoperative H&P states only: "The risks were explained to the family including death, stroke, bleeding, and they understand and wish to proceed, notwithstanding the increased risk of an emergency procedure."

(e) **MR #1296513 / ABS-007, admitted July 20, 2004.**

This patient was scheduled for a combined carotid endarterectomy and CABG. There is no dispute regarding the indications for either procedure, or the basic concept of performing them in sequence, with the carotid being done first. However, the patient developed chest pains and ECG changes in the holding area, and she had chest pain during line insertion in the OR. An intraoperative TEE revealed "global LV dysfunction." The operation went forward as planned, with the carotid procedure being performed first, despite the patient's acute global ischemia. NMA stated: "To proceed with carotid endarterectomy for asymptomatic disease in the face of global ischemia precluded any chance of salvaging the patient."

The key issues in this case revolve around the fact that Dr. Ennix did not see the patient that morning and was not present in the OR at the start of the surgery. He relied on others to keep him informed of developments at the time, and failed to assure, as the responsible surgeon, that appropriate decisions were made in response to the patient's changing condition.

Dr. Ennix told the NMA reviewers that he wishes he had been there, things could have gone differently if he had been present, and the case serves as a reason to change his practice in this situation. However, he did not concede the validity of the concerns entirely. He cited articles in support of performing the carotid before the CABG, and indicated that his conduct was consistent with standard practice at this facility. He also cast blame on the anesthesiologist and the vascular surgeon for not keeping him informed of the patient's condition. We see little merit in these points. The facts described in the articles were distinguishable from the facts in this case. We also do not believe that Dr. Ennix's performance, as described above, was consistent with the standard of care at this facility. He should have been present earlier in the morning and throughout the procedure, and taken personal responsibility for keeping abreast of developments and providing input as warranted.

As in the other cases, Dr. Ennix's documentation was deficient. The chart does not reflect his thinking behind the decision to perform a combined carotid/CABG and the attendant risks and benefits; nor does it describe the informed consent process, although he did obtain a letter from the family stating that he had met his responsibilities in that regard.

(f) MR #1124908 / ABS-010, admitted October 11, 2004.

NMA was critical of Dr. Ennix's judgment in delaying this patient's surgery despite a moderately positive dobutamine stress echo two days before and chest pain one day before the surgery; failing to protect the heart with cardioplegic arrest after unplanned conversion from off-pump to on-pump; and failing to place IABP or an arterial line before the patient left the OR. These are fair criticisms, although it could be argued that Dr. Ennix's decisions were reasonable judgment calls based on the information he presented.

The main problem, from the AHC's perspective, was Dr. Ennix's unavailability in the immediate post-op period, when the patient was unstable and experienced cardiac arrest requiring CPR only five minutes after arrival in CPU. Dr. Ennix had already left to return to his office across the street. Another surgeon, who was present by happenstance, opened the patient's chest in CPU and provided care as a Good Samaritan until Dr. Ennix returned after being summoned by the nurses. NMA expressed the opinion that Dr. Ennix's lack of immediate availability contributed to the patient's poor outcome. The AHC agrees with the criticism. Dr. Ennix's failure to remain at the patient's bedside during her period of instability immediately following surgery put her at great risk. Dr. Ennix emphasizes that his office is only five minutes away and that another surgeon was available to step in. We do not see these as mitigating factors.

B. Other Cases

In addition to the ten cases described in the NMA Report, three cases that occurred in the spring of 2005 were also reviewed by the AHC:

(1) MR #0578882

On March 23, 2005, while Dr. Ennix was attempting to perform a dual chamber pacemaker placement, one of the guide wires retracted into the patient intravascularly. The patient was taken to Interventional Radiology for retrieval of the guide wire, and ended up with a single lead pacemaker rather than the double lead pacemaker that was planned.

Wire retraction is a known risk of this procedure, but it is understood to occur very rarely and to be generally avoidable through appropriate caution. Those who were present during the procedure were interviewed, and did not report any obvious behavioral issues that may have caused the problem. However, another individual did report that Dr. Ennix seemed "less focused" than usual prior to the procedure that morning. Dr. Ennix discussed the matter with

representatives of the Medical Staff leadership, on April 12, 2005, and assured them that he was not under undue stress from this investigation or other issues and could practice safely.

Dr. Ennix told the AHC that he had attempted to avoid such a mishap by clipping the wire to the towel. He could not explain how the incident occurred anyway, except to say that the patient did well, "these kinds of things happen from time to time," and his take-back rate is comparable to that of his peers.

(2) MR #0847726

This is the case that, along with the NMA Report, precipitated the summary suspension of Dr. Ennix's privileges on May 10, 2005. It involved a 40 year old male who underwent AVR and MVR with resection of a subaortic ring for severe rheumatic heart disease on May 4, 2005. There were concerns that Dr. Ennix did not examine the patient on May 5, 2005, and that he falsified the medical record by entering a back-dated progress note the next day.

Dr. Ennix admitted that his May 5 note was actually written on May 6, but he said that he did not intend to give a false impression, and that he did see and examine the patient on May 5.

Dr. Ennix explained that he was occupied with other sick patients on the morning of May 5, and that is why he did not enter a progress note at the time. He produced a letter from a nurse stating that he "came into the patient's room to assess the patient, look at his hemodynamic monitoring values, his need for the ventilator and discuss the goals for the day." However, on May 12, the nurse made statements to the President of the Medical Staff that tended to undermine Dr. Ennix's claim to have actually examined the patient. She said that Dr. Ennix had asked her to write a letter verifying that he had seen the patient in the unit on May 5, because he had been suspended from the staff for not seeing the patient on that day and she was the only one who could help him. She was asked whether her letter meant that Dr. Ennix had done a "physical exam, listening to the heart and lungs, examining the chest tubes, the wound, etc.," and she replied: "actually, I didn't see him examine the patient at all. He may have done so at some other time during the day when I wasn't in the room."

The progress note, itself, does not contain information supporting Dr. Ennix's claim to have done a proper examination of the patient on May 5. It is scant, and includes lab data from the next day.

When the AHC met with Dr. Ennix, he said that he had learned from this and other cases regarding medical record-keeping irregularities and that he was committed to improvement.

(3) MR #904589

This patient recently underwent surgery that was planned as a combined CABG and mitral valve replacement. Based on the information that was available to the AHC, both procedures appear to have been indicated. Intra-operatively, a decision was made not to go through with the valve replacement. After discussing the case with Dr. Ennix, the AHC found that it did not raise any quality of care issues.

C. Other Information Regarding Medical Record Keeping Problems

As of May 31, 2005, the date of the AHC's letter inviting Dr. Ennix to discuss the issues in this investigation, he was on suspension for medical records delinquencies involving multiple cases. According to the documentation provided by the Medical Records Department, the problems included no dictated Operative Report for a patient who was discharged on April 18, 2005 (MR #00313381), and no dictated History and Physical for a patient who was admitted on January 19, 2005 (MR #001073312).

Dr. Ennix could not explain why these medical records were delinquent, except to say that he had gone through periods of duress and they seemed to have slipped through the cracks. He conceded that the delinquencies should not have happened.

It is important to note that Dr. Ennix has been clearly and repeatedly admonished over the years for his grossly substandard medical record keeping practices. For example, on August 13, 2001, he was sent a letter by Bruce Moorstein, M.D , then Chair of the Surgery PRC, stating:

> The committee attempted to review [MR #1000270, involving a death], but noted that:
> - As of 8/13 (nearly 2 months post op), there was still no dictated operative report in either the hard copy medical record or the EPR.
> - When compared to the perfusionist's and anesthesiologist's record, your handwritten operative note appeared to describe a different procedure than the one performed (no mention of the ACBs).
> - Your documentation following the 2nd surgery (re-op), fails to reflect that the chest was left open.
>
> The absence of the above documentation made it difficult to evaluate care as outside the standard, either intellectually or technically. This would also present problems were this case involved in litigation. We request you rectify the documentation issues by September 1, 2001.

As of October 15, 2001, according to a follow-up letter from Dr. Moorstein, Dr. Ennix still had not rectified any of the documentation problems in the above case or responded to the PRC. Ultimately, on October 18, 2001, Dr. Ennix dictated his operative report.

Similarly, on March 5, 2003, Leigh Iverson, M.D., Chair of the Cardiothoracic PRC, sent Dr. Ennix a letter regarding two cases (MR #1020408 and MR #1249702) involving death and return to surgery, respectively. The letter stated:

> These cases were reviewed for the reasons listed above. No care issues were identified, however, the Committee noted major documentation deficiencies. Both cases are incomplete for dictated operative reports, and immediate post-op progress notes. On MRN 1249702, the patient was returned to surgery for bleeding, and the re-operation report is not in the chart, nor is a progress note describing the findings and procedure.
>
> The Committee requests your assistance in correcting these deficiencies as soon as

possible, and appreciates your continued efforts to complete all documentation requirements in the future.

On June 10, 2003, Dr. Iverson sent Dr. Ennix another letter regarding a different patient (MR #582500) who had been admitted on February 20, 3003. The patient was admitted with a complete pneumothorax, and was later diagnosed with bullous emphysema. He underwent resection of the left lower lobe on February 28, 2003. Post-op, he remained critically ill and expired on March 3, 2003. The PRC could not find documentation of Dr. Ennix's decision to perform the lobectomy, and requested clarification. As of July 23, 2003, according to a follow-up letter sent to Dr. Ennix by certified mail, he had still not responded. On August 6, 2003, Dr. Ennix provided a response.

D. Personal Interviews

As mentioned in the Overview, above, we interviewed the Chair of the Department of Surgery, the Chief of the Cardiothoracic Surgery Service (three times), two other cardiac surgeons, three anesthesiologists, one staff member, and finally Dr. Ennix.

The Chair of the Department of Surgery described how he came to vote in favor of conducting this investigation, based on an anesthesiologist's expression of concerns regarding Dr. Ennix's minimally invasive procedures; his own concerns regarding the outcomes in these cases; the issues raised in the peer review process at Alta Bates; and the observation that, while Dr. Ennix is "technically good" in his regular cardiovascular cases, "lots of data falls out of the norm" and it "needs to be looked at."

Generally, the three other cardiovascular surgeons we interviewed (two of whom are in Dr. Ennix's medical group) are uncritical of Dr. Ennix. They do not have concerns regarding his judgment or skills, although one of them firmly expressed the opinion that Dr. Ennix should not do minimally invasive valve procedures. After reading the NMA Report, the Chief of the Cardiothoracic Surgery Service did agree that, overall, the results of the review were very thorough and valid. He also observed that, to some extent, Dr. Ennix has communication and team coordination issues, and tends to be overly-reliant on other people instead of taking a more hands-on approach.

One anesthesiologist described Dr. Ennix as being less decisive than his peers regarding on-pump and off-pump issues. Other comments by this anesthesiologist were: "Dr. Ennix's approach is that the human body will survive whatever is done – he can be sloppy – I do not know the degree [of impact] this has on patient outcomes;" "I depend less on him than I do with other surgeons when there is trouble;" "Of the four cardiovascular surgeons, Dr. Ennix is the one we pay most attention to in terms of patient care;" and "Dr. Ennix has a failure to think about the details." This anesthesiologist will not do minimally invasive procedures with Dr. Ennix, but said that in "normal cases," he "falls within parameters of what we are comfortable with." Subsequently, this anesthesiologist submitted a letter emphasizing the systemic issues associated with the "port access cardiothoracic surgery program," and expressing the view that no individual surgeon is at fault.

Another anesthesiologist said that he is generally uncomfortable working with Dr. Ennix, and compensates by being more assertive and vigilant than he is with Dr. Ennix's peers. He said that Dr. Ennix loses his focus on details and has to be re-directed, and that this happens frequently when Dr. Ennix takes phone calls or pages. He said that lots of potential problems are avoided by personnel picking up for Dr. Ennix. His concerns include poor judgment and poor patient selection. On the other hand, this anesthesiologist said that Dr. Ennix's vigilance and receptiveness to help have improved over the last year, while he has been under more of a microscope, and that the problems have been manageable because of the quality of the medical and nursing staff.

The third anesthesiologist made similar observations regarding Dr. Ennix's practice. He also said that he had witnessed the informed consent process in the case of MR #1124908 / ABS-010, above, and did not agree with Dr. Ennix's statement to the family that there was a peri-operative mortality rate of only 1% in this situation. He expressed the opinion, generally, that Dr. Ennix is cavalier about risks, does not connect with patient risks, and spaces out doing mundane things. He said that Dr. Ennix has seemed more distracted in the past year. He said that he would prefer not to operate with Dr. Ennix, from the standpoint of being less comfortable with him than with his peers, although his concerns were mitigated somewhat by Dr. Ennix's receptiveness to suggestions.

The staff member whom we interviewed said that he had been selected by his fellow technicians to call certain issues to the attention of the Medical Staff. He was not aware of this investigation. The concerns were that, over the last year, Dr. Ennix's skills appear to have diminished, he has become less sure of himself, and sometimes he seems to be slowing down. He added that he has also heard people saying that Dr. Ennix disappears at the end of cases and cannot be found.

E. Statistical Data

The AHC considered STS-adjusted statistical data for the period January 1, 1999 – April 30, 2005, showing an overall mortality rate of 7.4% for Dr. Ennix and an average of 3.8% for the other three non-Kaiser cardiovascular surgeons on Staff. It was noted that this is a two-fold difference. A trend analysis also shows that Dr. Ennix's mortality rate has been increasing through this period. The data, in both spreadsheet and graphic formats, are attached hereto as **Appendix B**.

Dr. Ennix attempted to demonstrate, primarily by breaking down the numbers to achieve large confidence intervals, that his record is statistically no worse than that of his peers. The AHC's interpretation of the data is that Dr. Ennix's record is much worse than that of his peers, and that there is no reasonable basis for ignoring or discounting this in assessing the safety of Dr. Ennix's practice.

F. Report from Forrest Junod, M.D.

As discussed in the Introduction section of this report, Forrest Junod, M.D., was engaged by the Alta Bates Medical Staff to review a series of cardiac surgeries performed by Dr. Ennix in 2002. Multiple problems were identified, much like the problems described by NMA.

For purposes of this investigation, the AHC does not consider these 2002 cases as important as the more recent cases discussed above. Also, as pointed out by Dr. Ennix, there were systemic problems affecting the cardiac surgery program at Alta Bates, which were sufficiently serious and pervasive to justify closing that program and consolidating cardiac surgery services at the Summit Campus. That said, the AHC does see Dr. Junod's report as being generally corroborative of the concerns expressed by NMA and others.

Among the more noteworthy elements of Dr. Junod's report is his comment on the importance of "good communication and understanding with all members of the operative team," as a means of minimizing risk in the difficult types of procedures Dr. Ennix performs. Dr. Ennix's weaknesses in this area are well illustrated by several of the cases we have reviewed, and by the manner in which he introduced minimally invasive valve surgery to this facility. He has not exhibited a great deal of appreciation for this problem, nor does he appear to have learned from his recent difficulties leading to the closure of the Alta Bates cardiothoracic surgery program.

G. Fairness of Peer Review Process

When Dr. Ennix met with the AHC, he argued strongly that this process has been unfair to him. His main contention was that he has been treated differently from other physicians, in that his cases were singled out for special scrutiny when the peer review process would have been put to rest in favor of other physicians. He noted that, in each of the cases reviewed by NMA, the initial reviewer at the Service PRC level found "no care issues;" and he pointed to information that, from his perspective, showed there was no valid or substantial basis for criticism in specific cases. He also characterized the NMA reviewers as "business men," suggesting that they were commercially motivated to find fault with his practice. He produced voluminous documentation referring to legal controversies in which NMA and the reviewers had been embroiled over the years, ostensibly to undermine their credibility as reviewers.

We have described the facts and circumstances leading to the appointment of the AHC. We were not involved in them, of course, but they are well documented. While it is true that the initial reviewer found "no care issues" in specific cases that have since come under serious scrutiny, it is clear that Dr. Ennix's peers have had substantial concerns about the quality of his practice, in general, for some time. At both Alta Bates and here, many issues were raised, and there were objectively sound reasons for delving further into the judgments, patient care events, and/or bad outcomes associated with all of the cases we have reviewed. The results show, in retrospect, that an intensive peer review process was well warranted.

With reference to NMA and its reviewers, we have inquired about the legal controversies identified by Dr. Ennix, and we are satisfied that there is no reasonable basis for disregarding or discounting their findings in Dr. Ennix's cases. Some of the issues plainly had no relevance to their practices as physicians; and the malpractice cases that were listed by Dr. Ennix, without revealing the results, were all resolved in favor of the physicians or, in a few instances, settled for small amounts.

It would be difficult, if not impossible, to reconcile every peer review decision with every other

peer review decision. Even if there were situations in which other physicians did not receive the scrutiny they deserved, for whatever reasons, it would not serve as a legitimate excuse for failing to investigate Dr. Ennix's practice under the facts as we know them. In any case, Dr. Ennix has presented no information demonstrating, or even suggesting the existence of, improper motives on the part of anyone.

IV. DISCUSSION AND RECOMMENDATION

NMA concluded that the cases reviewed, which had been pre-selected because of known problems, identified three major problems with the care delivered by Dr. Ennix: poor judgment, poor technique with minimally invasive valve and off-pump CABG procedures and grossly substandard documentation. According to NMA, if these patterns of care go uncorrected, it is likely that there will be future patient harm.

The AHC does not necessarily agree with every point made by NMA in its Report. For example, the AHC is not convinced that Dr. Ennix has exhibited poor technique in off-pump CABG procedures (although it is possible that, to some extent, technical errors have been concealed by Dr. Ennix's failure to document, and later failure to recollect, what actually occurred). The AHC also disagrees with NMA's determinations on specific issues, such as whether a TEE that was not documented in the chart was actually done. We attribute these disparities mostly to our familiarity with information that was not available to NMA. However, after carefully considering all of the issues and discussing them personally with Dr. Ennix, we must conclude that the NMA is correct in its overall assessment of the risks presented by Dr. Ennix's practice.

Perhaps the easiest finding to make is that Dr. Ennix should not be allowed to perform minimally invasive surgery. We believe that he would not disagree. The more difficult question is whether, and if so to what extent, he can be relied upon to meet the prevailing standard of care as a member of the Medical Staff with cardiothoracic surgical privileges.

We do not believe that Dr. Ennix can be relied upon to discharge the important medical record keeping responsibilities that are inherent to a cardiothoracic surgical practice. He claims that he is committed to improvement, but there is no reasonable basis for the Medical Staff to have confidence in this.

We also do not believe that Dr. Ennix can be relied upon to emulate his peers in their diligence and exercise of sound judgment in the care of patients. Even while under formal investigation, he failed to give adequate post-op attention to an unstable patient, and then attempted to conceal this with a backdated progress note. His explanations heightened rather than reduced our concerns.

We see two options:

Option 1.

We could recommend that Dr. Ennix's clinical privileges be restricted to surgical assisting, only, as they are now, but permanently. Essential features of the current

restriction are that Dr. Ennix cannot exercise any discretion in selecting procedures to be performed, obtain informed consent, make intra-operative decisions, document procedures, manage or follow patients post-operatively, make progress notes, make orders, or take call for inpatients or emergency situations. Based on the available information, and our responsibility to protect patients from reasonably foreseeable harm or substandard care, these measures are not difficult to justify.

Option 2.

We could recommend that Dr. Ennix's cardiothoracic surgery privileges be reinstated subject to strict proctoring requirements, including the involvement of a proctor (who would have to be a cardiothoracic surgeon) in every phase of his activities. The basic specifications would be:

- The proctor would oversee the patient evaluation and informed consent processes, and concur in the judgment as to which, if any, procedure(s) are indicated.
- The proctor would be present in the OR during the entire operation, and personally monitor the patient's post-op care at least daily until discharge.
- All documentation would be closely monitored by the proctor at least daily.
- In the event of any disagreement between Dr. Ennix and the proctor, on any issue, the proctor's judgment would prevail.
- If the proctor were to determine at any time that a patient's welfare is in jeopardy, the proctor would have the prerogative to take over the care of the patient immediately. Any such event would have to be reported as soon as possible to the President of the Medical Staff.
- It would be Dr. Ennix's responsibility to assure that the proctor prepares and promptly submits a written proctoring report in every case.

Option 2 would include a requirement that Dr. Ennix attend the full two-day Medical Record Keeping Course offered by the UCSD PACE Program. According to the current brochure, the cost is $1,250, and the next available session will be on October 27-28, 2005.

Option 2 would also include a warning to Dr. Ennix that, if he fails to comply with the above proctoring requirements or to meet the Medical Staff's standards of professional performance (including medical record-keeping) in any substantial way, at any time, it would be deemed grounds for summarily suspending or restricting his clinical privileges and/or recommending that his Medical Staff membership be terminated.

The above measures would remain in effect indefinitely, without exception (including ED call), unless and until they are modified or lifted by the MEC. They should be reviewed

by the MEC every six months. We would be willing to assist in this periodic review process, if requested by the MEC.

We would prefer Option 2 over Option 1. However, the practicalities of Option 2 are open to question. It would involve major burdens that cannot be imposed fairly on Dr. Ennix's peers against their will. If they are unable or unwilling to accept the responsibilities associated with this program, Dr. Ennix is unwilling or unable to cooperate fully, or the MEC determines that there would be any other substantial obstacles, it would be our recommendation, regrettably, that Option 1 be adopted.

Finally, at the end of NMA's Report, after the assessment of Dr. Ennix's practice, there is a section captioned "System Issues," in which NMA commented on perceived shortcomings in our cardiothoracic surgery program, generally, and offered suggestions for improvement. We recommend that this section of the Report (or a summary of it) be referred to the relevant Medical Staff departments and services for discussion and follow-up, as appropriate. (Any references to Dr. Ennix, by name, should be deleted.)

Respectfully submitted,

L D Paxton

Lamont D. Paxton, M.D.

Barry Horn, M.D.

Dat Ly, M.D.

APPENDIX A

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[redacted] Medical Audit
HR Consulting

Focused Review of Medical Records of Coyness L. Ennix, Jr., MD

May 3, 2005

Contents

Focused Review of Medical Records of Coyness L. Ennix, Jr., MD

May 3, 2005

NMA Review Process

NMA Systematic Reviews

NMA has been reviewing medical records to ascertain quality of care and utilization effectiveness for over two decades. During this time we have continually refined our review methodology and chart abstracting instruments. Currently, reviewers use a structured review protocol that guides them in characterizing both utilization and quality issues in a quantifiable fashion. All reviews are conducted by expert physicians whose board certification is matched to the cases they review.

Once completed, each review is assessed by a senior NMA physician-review supervisor for completeness and internal consistency. If an inconsistency is identified, the case is referred back to the original reviewer for re-review, with verbal and sometimes written feedback.

Reviewer Internal Quality Control

NMA's internal quality control process examines prospective reviewer's expertise and recognition in their specialty, including training, experience, board certification and academic appointments. All reviewers are interviewed by a senior physician-member of the NMA audit team who evaluates their experience and effectiveness in chart review, including their attitudes toward judging peers. Prospective reviewers are then sent a set of specialty-relevant test cases to evaluate the quality of their medical chart review capabilities. If the quality and accuracy of their review meets NMA standards, they are accepted as reviewers. The first few reviews of each new reviewer are scrutinized by a senior NMA physician-review supervisor who then works with the reviewer to further standardize formatting and accuracy of their responses. This iterative process continues on an ongoing basis.

Quality Review

NMA reviewed 10 cases, as supplied by the hospital. The qualifications of the reviewing physicians are provided in Appendix 1. Supplemental information provided by the hospital and Dr. Ennix is listed in Appendix 2. Copies of the review worksheets from the cases reviewed in depth are attached as Appendix 3. References cited in this report are listed in Appendix 4.

Introduction

NMA reviewed nine cases from January 16, 2004 to October 11, 2004 and one case from January 9, 2002 where Coyness L. Ennix, Jr., MD performed cardiac surgery. Peer review at the hospital had identified problems in all of the cases, which were then sent to NMA for outside review. Four of the cases involved minimally invasive valve surgery and six involved CABG surgery, three of which were initially planned as off-pump procedures. One patient arrested, was placed on extracorporeal membrane oxygenation (ECMO) and transferred to another hospital for salvage LVAD; six others died.

In addition to reviewing the records of these 10 cases, NMA reviewed written correspondence from Dr. Ennix and held two phone conferences with him (March 19, 2005 and March 26, 2005) to obtain further clarification of events. The conclusions of this report are based on the documentation as stated in the medical record, as well as supplemental information provided by the hospital and Dr. Ennix, as listed in Appendix 2.

The problems identified in this review are organized into three sections:

1. Poor judgment
2. Poor technique
3. Substandard documentation.

We have grouped each case reviewed into the category that best reflects the primary problem of the case. When findings were relevant to a different type of problem, these are discussed as well.

The review determined that Dr. Ennix demonstrated poor judgment in five cases, one of which also had technical problems. The poor judgment led to death or arrest and ECMO in four cases and severe complications in another. Five other cases had technical problems that led to death in two cases,[1] complications in one and possible future harm in another. In addition, the review found that Dr. Ennix has grossly substandard documentation.

Five Cases of Poor Judgment (One with Technical Errors) Leading To Death/Arrest (Four Cases) or Severe Complications (One Case)

ABS-010 Delay in Surgery and Intraoperative Errors Leading to Arrest and ECMO

This 41-year-old African-American woman presented to the ER on 10/11/2004 with a five to six-week history of chest pain, increasing over past two days. Her ECG revealed inverted T waves in V3-V5, but her Troponin was normal at 1.4. A dobutamine echo on 10/12/2004 was abnormal with diffuse ECG changes, chest pain, and distal inferior and apical hypokinesia. An angiogram two days later on 10/14/2004 revealed 90% left main disease. Dr. Ennix first saw the patient on 10/14/2004 and performed a CABG on

[1] A third patient died, but not necessarily due to the technical errors [ABS-006].

10/15/2004 at 1524 (anesthesia started at 1355). Despite the normal ventricular function described on intraoperative TEE at the beginning of the procedure, the patient had complications during the operation. During the IMA takedown, i.e. before the patient would have been placed on cardiopulmonary bypass, the decision was made to convert from planned OPCAB (off-pump coronary artery bypass) to on-pump. Shortly after arriving in the ICU, the patient arrested. Ultimately, she required ECMO and was transferred to another hospital for salvage left ventricular assist device (LVAD).

Issues

1. **Poor judgment in delaying surgery.** Despite the moderately positive dobutamine stress echo on 10/12/2004 and chest pain on 10/13, cardiac cath was not performed until 10/14. When the angiogram showed critical left main disease, plans should have been made for a balloon pump to preclude/reduce ischemia if the patient developed new or worsening chest pain. This was not done. On the morning of 10/15 she had a stat ECG and was started on IV NTG. Apparently Dr. Ennix was not notified of the pain on the morning of 10/15. The cardiologist and surgeon share the responsibility for this delay.

2. **Failure to fully protect the heart after unplanned conversion from off to on-pump.** The cause of the patient's instability during IMA takedown that required conversion to on-pump is not clear. Once the patient had instability, it was necessary to go onto bypass. Once on bypass, Dr. Ennix failed to fully protect the heart with cardioplegic arrest, including use of retrograde perfusion to completely perfuse the LAD territory, which would have allowed more technically precise anastomosis to the LAD. Continued beating-heart surgery likely played a role in the immediate postop arrest of this 41-year-old woman who had normal ventricular function at the beginning of surgery.

3. **Failure to place IABP or arterial line before leaving OR.** Placement of IABP would likely have prevented subsequent life threatening problems. At a minimum, the surgeon should have placed an arterial line in the femoral artery for quick IABP access. The failure to provide IABP protection made it even more important that the surgeon be immediately available during the early postoperative period.

4. **Unavailability of surgeon in immediate postoperative period.** Based on anesthesia and nursing records in the CPU, the patient left the OR at 1927, arrived in CPU at 1930 and had cardiac arrest requiring CPR at 1935—only five minutes after arrival in CPU. The surgeon was not available to open the patient's chest in the CPU, which was done by another physician. Dr. Ennix should have been at the patient's bedside.

   The delay in IABP/surgery, the inadequacies during this operation and Dr. Ennix's lack of immediate availability when the patient arrested resulted in this patient's poor outcome. She was alive only because of ECMO and transport to another hospital for salvage LVAD.

During the March 26, 2005 phone conference, Dr. Ennix stated he was immediately available, but across the street at his office, which is about 5 minutes away.

He stated that between the end of surgery at 1844 and 1920, the patient was being prepared to be taken to the CPU.[2] During that time, he indicated he was "no doubt talking to family, writing notes, seeing other patients." After surgery, the patient was stable with BP of 210. "I no doubt passed thru the ICU on way to speak with the family during that period." At some point, he indicated he did leave the hospital and go over to his office that is 5 minutes away:

> Had there been any sense the patient was unstable, I would have been at the bedside. They called me at 7:45 or 7:50 (from nurses' notes).[3] Apparently, the patient got into trouble at 7:30 or 7:35. Instead of calling me, the anesthesiologist wanted to do a TEE, which I thought this was ill advised.[4] The other surgeon's note states 7:15, but this is incorrect. Nurses' notes indicated they called me 1945 to 1950. He (the other surgeon) is correct when he says patient went into sinus rhythm with BP >100. I answered immediately and came right back to the hospital. The other surgeon was called to assist about 1948, not 1915 as stated in the record.[5]

Dr. Ennix then indicated that it took him about 5 minutes to get back to the hospital and another 3-5 minutes to change out of his old scrubs and put on clean ones. He said that when he arrived, he met the other surgeon in the hallway and he and the other surgeon took the patient to the OR. The record indicates the patient was in OR around 2000.[6] He assisted the other surgeon with putting the patient on the OR table.

Dr. Ennix indicated that he did not accompany the patient and anesthesiologist to the CPU. However, had there been any hint the patient was unstable, he would have been right there.

In his letter of March 28, 2005, Dr. Ennix reiterated that the times stated by the other surgeon were incorrect and that he was available in the OR within approximately eight minutes after being called.

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[2] The anesthesia record says the surgery ended at 1844. The ICU nurses' notes state that the patient was admitted from OR at 1930.
[3] Nurses' notes states that the patient needed CPR at 1935 and that they notified Dr. Ennix at 1945.
[4] The anesthesia record states that the TEE was started at 1942 in the ICU and ended at 2015.
[5] 1915 is from the other physician's progress notes, which stated, "around 7:15pm."
[6] The nurses' notes state that the patient was transferred to the OR at 1958.

In conclusion, Dr. Ennix was not available to open the patient's chest in the CPU, which had to be done by another physician. Dr. Ennix should have been at the patient's bedside.

5. **Substandard documentation.** There was no detailed documentation of discussions with the patient and family regarding the operative indications and risks. The documentation regarding consent was also inadequate.

   Dr. Ennix provided a letter authored by the parents of the patient dated February 18, 2005. The letter states:

   > Dr. Ennix asked us to give you an assessment of our feelings toward him and how he related to us before, during and after the surgery....We understood going in that heart surgery was serious and that there were risks including a possibility of death....Before the original surgery, Dr. Ennix was very kind in explaining the surgery and the risks to [patient name removed].

ABS-007 SEQUENTIAL ERRORS IN JUDGMENT LEADING TO DEATH

This 63-year-old woman with a history of MI in 1983 presented with a six-month history of typical exertional chest pain and recently increasing symptoms. An outpatient stress echo was highly positive with chest pain and abnormalities were seen in three segments on the echo. A cath on 7/20/2004 showed 3-vessel CAD with "99%" ostial LAD stenosis. The patient was admitted because of chest pain during the cath. Dr. Ennix saw the patient and recommended CABG, but surgery was postponed until 7/23 to workup asymptomatic carotid bruits. [The vascular surgeon's note documented the absence of symptoms, except for possible amaurosis fugax on the right about three years earlier.] Carotid duplex was positive and carotid angio on 7/22 confirmed right internal carotid occlusion and showed 90% left internal carotid stenosis. The patient had chest pain during that procedure, again that night and finally was brought to the OR at 1351 on 7/23. She had chest pain and ECG changes in the holding area. During anesthesia induction, a preop TEE in the OR showed acute LV global dysfunction; the vascular surgeon then performed the carotid procedure, followed by a carotid angiogram, following which Dr. Ennix performed the CABG. While Dr. Ennix was dissecting the internal mammary artery, the patient had to be placed on cardiopulmonary bypass emergently. Dr. Ennix noted evidence of probable acute apical injury. He performed a CABGx2, but the patient suffered cardiac deterioration after reversal of Protamine. Despite a second cardiopulmonary bypass run, IABP and inotropes, the patient could barely be weaned from cardiopulmonary bypass. She left the OR in unstable condition with her sternum left open and died of ventricular fibrillation shortly after leaving the OR.

Issues

1. **Several-day delay before performing CABG.** While this patient was having chest pain during the cath on 7/20, the situation did not categorically demand

operation on the day of the angiogram. The LAD lesion appeared threatening and that probably should have prompted maintenance on IV Heparin, and/or insertion of an IABP until the operation. Moreover, she had several episodes of chest pain requiring PRN NTG while at bed rest several hours after the angio. Those episodes should have prompted a rethinking about the timing of the CABG; it should have been performed no later than the morning of 7/21.

2. **Failure to preoperatively appreciate risk of intraoperative stroke from atherosclerotic aorta.** In the OR, this patient was found to have a severely diseased ascending aorta. This should have been appreciated preoperatively since heavy aortic calcification was clearly visible on shots from the ventriculogram on 7/20. This was not mentioned by either the cardiologist or Dr. Ennix. The diseased aorta posed more risk of intraoperative stroke than the carotid disease.

3. **Failure to perform CABG before carotid.** The decision regarding the management of carotid and coronary artery disease is complex. If the patient is stable, literature can be cited to support either staged, separate procedures or combined carotid endarterectomy and CABG at the same operative setting. Therefore, the initial decision to workup the asymptomatic bruit and plan to do concomitant CABG/endarterectomy is defensible (and in fact, supportable by the 2004 AAA/AHA Guideline Update for Coronary Artery Bypass Surgery), as long as the patient is maintained free of symptoms while in the hospital and the workup of the carotid is done expeditiously and limited to noninvasive studies. (Given the clear-cut findings on duplex and the ongoing chest pain, it is not clear that the carotid angiogram was indicated.) It is likely that the best chance of a good outcome would have been achieved with prompt CABG on the morning of 7/21, the day immediately following the cardiac angiogram, with plans to cannulate the femoral artery instead of the diseased aorta, while carefully maintaining a mean blood pressure above 80.

   The critical error, however, occurred on the day of the operation. The medical record clearly documented that the patient had chest pain and ECG changes in the holding area and was "rushed into OR" where she had chest pain during line insertion. An intraoperative TEE revealed "acute global LV dysfunction noted during induction." Given those findings, the planned carotid procedure should have been abandoned, and the patient should have been placed immediately on cardiopulmonary bypass.

   To proceed with carotid endarterectomy for asymptomatic disease in the face of acute global ischemia precluded any chance of salvaging the patient. This patient had progressive cardiac deterioration shortly after Protamine was administered and suffered a massive intraoperative MI. Despite a second bypass run, IABP and inotropes, she died shortly after leaving the OR.

   Dr. Ennix failed to incorporate the patient's changing clinical condition into his decision making. The severe myocardial damage suffered during the combined

operation resulted in death. The outcome may well have been different if Dr. Ennix had focused on treating the acute cardiac situation.

During the phone conference on March 26, 2005, Dr. Ennix explained that he had not seen the patient preoperatively the morning of surgery and was not present in the OR when the vascular surgeon performed the carotid surgery. Rather, he was nearby in the ICU. He had seen the patient the previous day and talked to the cardiologist the morning of surgery. Dr. Ennix said the cardiologist told him that the patient had had some pain the previous day, but did not mention pain that morning. His impression from the cardiologist was that the patient was stable and that they were going ahead as planned (carotid, followed by CABG). Dr. Ennix indicated that he was not apprised of the pain that the patient had on the way to the OR prior to surgery.

During the same phone conference, the NMA reviewer asked Dr. Ennix that given a combined procedure being done for crescendo angina on the heart side and stable, asymptomatic disease on the carotid side, how could he exert his appropriate role in agreeing to go ahead as planned, or state the cardiac status took precedence and the carotid would have to wait, if he was not in the OR. Also, the reviewer asked that if he was not in the OR, how could he consider other alternatives such as putting in a balloon to demonstrate that global dysfunction was resolved, ECG changes were resolved, or determine if the patient needed to go onto bypass, and determine that once stable, the carotid surgery could proceed.

Dr. Ennix responded that the reviewer's point was well taken. He continued by saying that in his own defense, he was in the area in the ICU, but that he wished the anesthesiologist or vascular surgeon had apprised him of the problem. He was not aware of the TEE findings until he was in the OR and the vascular surgeon was half way through the surgery. Regarding IABP, he stated that he liberally inserts them. In this case, when he was told the patient had global ischemia, he felt the patient would be on bypass imminently and probably had atherosclerotic femoral vessels. He said that if he had been in the room, things could have very well gone differently. He felt that this was a failing and regretted not having been in the room. He went on to say that in this facility, since there are separate groups (carotid and CV surgery), it was rather routine. He said that the doctors check on things, but being intimately present is not routine. In this case, Dr. Ennix said he wished he had been there, and that this is a reason to change his practice in this situation.

The reviewer then pointed out to Dr. Ennix that when he came into the OR and knew he would be on-pump soon, that he was not concerned enough about the hemodynamic changes. Dr. Ennix went ahead and took down the mammary before he went on-pump. Dr. Ennix responded that he can take down the IM fairly expeditiously (probably 7-10 minutes), which approximates the time that an assistant can take a vein. Going on bypass and then taking the IM down would have been an option and would have saved a few minutes. He stated that he felt if

he stuck to his routine, things would go smoothly.

The reviewer then commented to Dr. Ennix that he stuck to his routine and the vascular surgeon stuck to his routine. The reviewer did not understand how someone could do a complete carotid angiogram in the face of global LV dysfunction on echo, chest pain and ECG changes in the holding area. Sticking to routine in the face of cardiac ischemia did not seem to be a good strategy, to which Dr. Ennix replied that he agreed. Doing the angiogram was ill advised. In retrospect, he said, he wished he had gone on-pump first.

In his letter Dated March 28, 2005, Dr. Ennix, argued at length that combined (carotid and CABG) procedures are routinely performed and this was a "reasonable and the safest approach...." He included several articles supporting the combined approach. What he failed to address, however, was why, in the face of increasing cardiac instability, they did not change the approach to one that first addressed the urgent clinical condition, cardiac ischemia. In the articles he cited, both the carotid and cardiovascular teams are in the OR from the beginning of the procedure. One of the teams harvests the SVG or internal mammary during the carotid procedure (concomitant, not sequential procedures).[1] Only 7% of their procedures were rated as emergent, and in the discussion, in addressing the appropriate timing of carotid endarterectomy, they cite another study referring to patients "whose coronary disease could be stabilized to permit initial carotid endarterectomy before grafting...." The method section in a second study cited by Dr. Ennix states they routinely perform the CEA with the chest open[2] while a third indicated they do so in unstable patients, stating, "...in patients in unstable condition, carotid exposure, median sternotomy, and cannulation were performed simultaneously."[3] In a fourth study, "carotid endarterectomy and lower extremity vein harvest were performed simultaneously."[4]

In conclusion, the conservative approach cited in these articles is different from that taken in this case in which Dr. Ennix was neither aware of the cardiac instability nor in the OR during the carotid endarterectomy. While the cardiologist, vascular surgeon and anesthesiologist bear some responsibility, it was ultimately Dr. Ennix's responsibility to assure that the patient received bypass surgery when it was indicated.

4. **Failure to document reasoning/consent for carotid/CABG vs. CABG.** The documentation regarding the decision to perform combined carotid/CABG was grossly inadequate as was the documentation regarding discussion with the family. However, as indicated below in the letter from the patient's son, it appears that Dr. Ennix did explain the additional risks, but failed to document this in the record. Nevertheless, the chart documentation remains deficient. Dr. Ennix provided a letter authored by the son of the patient dated February 18, 2005. The letter states:

Dr. Ennix asked me to write to you to confirm that all of us

understood the seriousness and the risks of mother undergoing this surgery. We understood the additional risk of the disease in her neck arteries and understood why they needed to be operated on to avoid stroke. Dr. Ennix spent ample time with my mother on several occasions, describing the operation and explaining why she needed the operation. My mother was also made aware and understood the risks involved including stroke and death.

However, the chart lacks discussion of the surgeon's thinking and the ramifications of the two approaches. Since this patient had recurrent episodes of chest pain in the hospital, there should have been additional notation regarding the appropriateness of further delay of CABG and of the combined procedure. There was no mention of this in the chart.

Nevertheless, it is unlikely that the patient/family were accurately informed regarding the risks/benefits of the option initially selected (concomitant CABG/carotid) and even more unlikely that they were involved in any discussion of the changing circumstances, which should have prompted reconsideration of the initial plan, or of the risk of cardiac catastrophe that would be associated with the combined operation while the patient had an unstable cardiac situation.

ABS-005 POOR JUDGMENT IN PERFORMING EMERGENCY CABG LEADING TO DEATH

This 57-year-old diabetic woman with renal failure on chronic peritoneal dialysis presented with unstable angina and acute Q-wave MI on 2/27/2004. She had an emergency cath at 1820 on 2/28/2004 that showed 100% RCA occlusion and other disease. Her BP was 60 in the cath lab. An IABP was placed in the cath lab and the patient stabilized with her BP rising to 100/66. Later that evening at 2230, Dr. Ennix performed an emergency CABG. The patient developed shock in the OR that never reversed and died on the first post-op day. Autopsy revealed a massive transmural infarct of the posterior left ventricle.

Issues

1. **Poor preoperative evaluation.** The cath was poorly performed; the views were limited and the findings overstated. Two NMA reviewers agreed with the cardiologist that the RCA was 100% stenosed and the circumflex 70% stenosed. However, both independently concluded that the disease in the left main (operator 50%, reviewers < 30%) and LAD (operator 90%, reviewers < 40%) was overstated. It is sometimes difficult to document left main disease, and the operator may have recognized dampening in the catheter, which would indicate severe left main disease. However, there is nothing documented in the medical record to suggest this. The operator could have further clarified the status of the left system with IVUS or FFR; neither was performed. In addition, this patient needed a right-sided ECG and echo to evaluate further the status of the right ventricle, but neither was performed.

Dr. Ennix's handwritten consult note stated "severe three-vessel disease... Emergency angiography shows the following: LVEDP 6 ___ gradient, 50% LM, 90% LAD, 98% LCX, 90% OMB, 100% mid RCA (L→ R collaterals)...." The note did not state whether he reviewed the angiogram personally; the wording and description are identical to that found in the cardiologist's note.

During the phone conference on March 19, 2005, Dr. Ennix indicated that he had great respect for the cardiologist, but he was not certain that he (Dr. Ennix) had personally reviewed the angiography films, and if he had, he might have come to different conclusion.

In a followup letter dated March 21, 2004, Dr. Ennix stated that, "This patient was referred for emergency surgery by the cardiologist because on reviewing the cineangiogram together, it was our feeling that the diseased vessels were not suitable for catheter intervention....He used a 6 French or 2mm catheter, which invariably damped the ostia at the left main and the right such that hypotension occurred." However, neither the cardiologist's handwritten nor dictated notes mention the dampening.

The statement in the letter, "on reviewing the cineangiogram together," is in conflict with Dr. Ennix's statement from the March 19, 2005 call where he indicated he was not certain that he (Dr. Ennix) had personally reviewed the angiography films, but if he had, he might have come to a different conclusion.

2. **CABG not indicated when performed.** This patient had an acute MI complicated by shock (cath report indicated BP of 60) requiring IABP. Surgery was not indicated when Dr. Ennix performed it. The patient was stable on the IABP and her low filling pressures indicated that her hypotension was more likely due to volume depletion than to ischemia alone. Had the RCA been opened by PCI and surgery delayed for several days, the outcome would likely have been more favorable. Alternatively, surgery could have been delayed until the patient had further stabilized. The risks and benefits of surgery could then have been re-assessed at that time.

   During the phone conference on March 19, 2005, Dr. Ennix indicated that he did not want to operate on this woman, but that the cardiologist indicated he had nothing to offer the patient. The NMA reviewer stated that the echo showed the left ventricle to be in reasonable condition, and that the patient should have had a right-sided ECG to confirm RV infarction. Given the findings, the chance of getting through surgery was remote. Regardless of what the left sided vessels showed, the outcome might have been different had the RCA been opened. The NMA surgical reviewer felt that the RCA should have been opened in the cath lab, and the patient stabilized for 5-6 days before performing surgery. An NMA cardiologist also independently reviewed the case and stated he felt the RCA was likely amenable to PCI. He added that "although collaterals are seen going to the RCA from the left coronary system, a clear definite target is NOT visualized,

bringing into question whether bypass surgery (specifically of the RCA—the likely culprit) was advisable.... I think most experienced interventionalists would have just gone and opened the RCA."

Dr. Ennix supplied a letter dated March 21, 2005 in which he stated that he and the cardiologist felt that the left main and the whole left system were diffusely diseased with no normal reference throughout the left main artery, and this is why he estimated 50% obstruction. Despite an ECG showing probable inferior infarction and anterolateral ST-T abnormalities and a Troponin of 50 on the day of the cath, Dr. Ennix's letter stated that the cardiologist felt it would be ill advised to open the RCA because "one, opening up the right would be of minimal benefit to the ischemic left side and two, and perhaps more importantly, the cardiologist felt that since hypotension occurred each time the right side ostia was engaged, his attempting to open this vessel could lead to rapid instability and a 'cath lab crash.'"

The record does not support this. First, the cardiologist's cath note from 2/27/04 (written one year before Dr. Ennix's letter of 3/21/05), did not mention dampening. Second, the cath record stated that the patient was hypotensive throughout the entire angiogram up until an intra-aortic balloon was placed, with systolic blood pressure varying from 56 to 86 mm Hg until the balloon pump was inserted. There was no differential with the engagement of the RCA and the low blood pressures were documented with LV tracings and left coronary artery injections. Third, the patient had a rather low left heart filling pressure at the time she was hypotensive, suggesting that she was hypovolemic, a finding frequently seen with an RV infarction. Fourth, there was no objective evidence for left coronary ischemia no matter how diffusely diseased the left coronary system appeared.

In conclusion, this patient had a right sided infarction and an RCA culprit lesion. The degree of left sided disease was overstated by the cardiologist and Dr. Ennix. Most important, there were two safer options that could have been, but were not chosen by Dr. Ennix and the cardiologist. First, and ideally, the RCA should have been treated by PCI. Second, even if the PCI were not performed, once her angina and hypotension were relieved by IABP, the patient should have been stabilized and surgery delayed. Dr. Ennix's decision to take this patient to surgery emergently placed the patient in unnecessary danger and is not the standard approach in use today.

3. **Substandard op note.** The operative note in this case had numerous transcription errors, indicating that it was not reviewed by the surgeon and corrected. The only statement regarding consent states: "The risk, plan and technique have been discussed with the patient and her family." The op note was dictated the same day as the operation, but not signed until two months later (5/04/2004).

During the March 19, 2005 phone conference, Dr. Ennix indicated that his

documentation was not what it should have been. It should be noted, that none of the findings alluded to by Dr. Ennix during that call were included in the chart.

ABS-008 CONTRAINDICATED SURGERY LEADING TO DEATH

This 72-year-old woman with diabetes and hypertension presented to the ER on 5/6/2004 with a 3-4 hour history of chest pain and ECG showing inferolateral ST-elevation. She was taken emergently to the cath lab at 1356 and started on Integrilin and Heparin. The angiogram revealed a 90% mid-RCA lesion and 70-80% lesions in the LAD. While awaiting cardiac surgery consultation, her BP fell to the 80s and she was diagnosed as having a retroperitoneal bleed. Her BP stabilized and she had a CT scan at 1554 confirming the retroperitoneal bleed. Dr. Ennix took the patient directly to the OR where he performed a CABGx4. The operation was complicated by severe coagulopathy and the patient ultimately died of multiorgan failure on the sixth POD.

Issues

1. **Surgery contraindicated when performed, resulting in death.** This patient had an ACC/AHA Class IIB indication for CABG: primary reperfusion of ST segment elevation MI within 6-12 hours. However, there was a major contraindication to proceeding with emergency CABG at the time Dr. Ennix performed the operation. First, although the patient was acutely hypotensive immediately following the retroperitoneal bleed, she had stabilized and her blood pressure was initially 266/140 followed by 220/130 prior to surgery. Second, Integrilin had been stopped at 1535, less than one hour prior to the patient arriving in the OR at 1619 (surgery started at 1742). Given the absence of an immediate indication for surgery and the high risk of bleeding from Integrilin, the surgery should have been delayed.

   The patient's LVEDP was very low, indicating either relative volume depletion and/or a response to the vasovagal episode that occurs with blood in the retroperitoneum. The preferred course would have been to provide optimal blood/fluid resuscitation, perhaps with the aid of a Swan-Ganz Catheter. The Integrilin should have been immediately discontinued and surgery delayed as long as possible, until the risk of coagulopathy diminished. Given that the patient's BP was 220 prior to surgery, there is a very good chance she would have remained stable for at least 4-6 hours, by which time the risk of coagulopathy would have decreased substantially. She could have been reevaluated at that time and based on her condition, surgery either could have been performed or further delayed.

   Another, perhaps lower risk, option would have been to stabilize the cardiac situation by PCI. Given that the patient's ST-elevation was inferolateral, there was a reasonable likelihood that the RCA was the culprit lesion and could have been treated with primary PCI, with or without stent.

   However, there was no documentation in the chart regarding the pros and cons of proceeding with PCI of the RCA, nor does Dr. Ennix document why he chose to

proceed immediately to surgery once the patient had stabilized. His decision to operate in the presence of an iatrogenic coagulation disorder and retroperitoneal bleed resulted in need for massive transfusions of blood components, including 11 units of packed red cells, 4 units of platelets, 11 units of fresh frozen plasma and 20 units of cryoprecipitate. As a result, the patient developed multiorgan failure and died on the sixth POD.

On the March 26, 2005 phone conference, Dr. Ennix was asked why the RCA was not identified as the culprit lesion and a PCI performed, since this patient was at enormous risk for surgery. He indicated that the cardiologist was a senior and well-respected cardiologist and that they certainly talked about this possibility. However, the cardiologist felt there was little chance of PCI being successful, he felt there were two culprit lesions, the mid RCA and the distal LAD, and felt the patient was extremely unstable, and therefore, was uncomfortable approaching any of the vessels. Dr. Ennix said that the best chance would be surgery because of the extensive disease and ongoing ischemia. Dr. Ennix said he wished the cardiologist would have been able to open the RCA, and there were many reasons he would have preferred not to operate.

When asked, given the acute inferior MI, whether it not reasonable to conclude that the RCA was the culprit lesion, Dr. Ennix responded that "clearly the infarction was caused by RCA lesion" and in retrospect, he wished they had done the PCI. However, Dr. Ennix stated that it was the feeling of the cardiologist "and I agree, that while surgery carried high risk, but with the sluggish anterior wall in addition, she would be better off trying to operate."

Dr. Ennix was asked why he did not try to wait a few hours to allow the Integrilin to wear off in the face of the fresh retroperitoneal bleed, given that the patient had stabilized (BP 220 with IABP). He indicated they discussed this with the vascular surgeon, who was present in the OR, and examined the CT scan and felt the retroperitoneal bleed would not be a problem. On the other hand, there was ongoing ischemia and they felt this period of normal BP might have been transient and offered a window of opportunity. They felt the ongoing ischemia needed to be fixed soon. In addition, Dr. Ennix stated that the cardiologist felt strongly that revascularization needed to be done.

Dr. Ennix was asked if he faced the same situation tomorrow, would he accept the cardiologist telling him that PCI was too risky. Dr. Ennix responded that they have had similar discussions about the relationship between cardiologists and CV surgeons in their community and they are influenced by the cardiologists' thinking—sometimes to their own peril. He said he could not push the cardiologist to do a PCI, and felt that refusing to operate did not seem like the moral thing to do. He said he knew that the cardiologist would not take on the case, and added that in the future, no doubt, this experience would make him far more assertive in these situations.

In his March 28, 2005 letter, Dr. Ennix stated that on reviewing the cinearteriography, the extent of coronary disease and patient's instability precluded safe intervention by the cardiologist, and that it was unclear whether the LAD or RCA was the culprit lesion. (He included a letter from the cardiologist on the case stating similar conclusions.) Dr. Ennix further argued that while operating was high-risk, that medical therapy carries an even higher risk. His letter did not indicate why surgery would be safer than PCI in this unstable patient.

In further evaluating the appropriateness of PCI of the RCA, NMA had this case independently reviewed by an interventional cardiologist. The cardiologist reviewer indicated that the patient presented with an inferior MI, and that the angiogram demonstrated culprit occlusion of the RCA and diffuse disease of the left coronary system. (There were relatively few images taken during the diagnostic cath.) The reviewer stated that the lesion was not overly complex and that once the patient had stabilized, 90% of interventionalists would have proceeded with PCI of the RCA.

In conclusion, there were two safer and preferable options available. First, had Dr. Ennix waited a few hours for the Integrilin to wear off, the patient would likely have had a much safer operation; second, the patient could have had a much lower risk procedure, a PCI of the RCA. As the cardiac surgeon, it was Dr. Ennix's responsibility to determine when and if it was safe to perform surgery.

2. **Substandard consent/documentation:** It is impossible to know what was communicated to the patient and/or family regarding the risks and benefits of immediate vs. delayed surgery, or of PCI vs. CABG because there was no documentation in the chart to that effect. Dr. Ennix's preop H&P states, "The risks were explained to the family including death, stroke, bleeding, and they understand and wish to proceed, notwithstanding the increased risk of an emergency procedure." There was no written consent in the chart for CABG.

ABS-002 POOR JUDGMENT AND PREOP EVALUATION AND CONVERSION TO PARTIAL STERNOTOMY COMBINED WITH TECHNICAL ERRORS LEADING TO POSTOPERATIVE RESPIRATORY FAILURE

This 37-year-old woman presented with severe aortic stenosis on echo. Dr. Ennix performed an AVR on 1/28/2004, using a small prosthesis (17 mm). He started the case as minimally invasive and then converted to a partial sternotomy procedure. During the surgery that lasted over 10 hours, the patient received 11 units of RBCs, 12 units of FFP, 8 units of platelets and 24 units of cryoprecipitate. Post-operatively, the patient developed respiratory failure. She was discharged on 2/05/2004 in stable condition.

Issues

1. **Inadequate preoperative evaluation.** Dr. Ennix used poor judgment in operating on this patient in the absence of a preoperative cardiac cath. This is a serious omission in a 37-year-old presenting with chest pain and an abnormal ECG. In

addition, the echo report is brief; a more thorough report might have facilitated better preop planning of valve size and root issues. Anyone undergoing AVR should have a complete cardiac echo and cath.

During the March 19, 2005 phone conference, Dr. Ennix indicated he was not sure that a coronary angiogram had been done, but that the cardiologist felt that the patient did not have CAD. Nevertheless, it is the cardiac surgeon's responsibility to be certain that a complete preop evaluation has been performed prior to taking the patient to surgery.

2. **Conversion to partial sternotomy.** During the procedure, Dr. Ennix converted from a minimally invasive to partial sternotomy that he attributed to a "small aortic root." Although not stated in the op note, the conversion was, presumably, to get better exposure.

3. **Greatly prolonged surgery time.** The operation lasted over 10 hours and required large amounts of blood products. In total, the patient was in the OR for 14 hours.

   During the March 19, 2005 phone conference, Dr. Ennix indicated that the operation took a long time because the anesthesiologist was not experienced in putting in this type of neck line; the approach through the 3rd intercostal space takes longer; being among the first few minimally invasive cases, he was extra meticulous and changing from the larger valve (#19) took time. He stated in retrospect, he wished he had documented the blood products. However, he indicated, it was documented elsewhere in the chart.

4. **Prosthesis too small.** Dr. Ennix implanted a 17 mm Jude prosthesis in this patient who weighed 135 pounds. While the substandard operative note (see below) did not detail what transpired in the OR, it was likely that Dr. Ennix used a valve that was too small. It is extremely rare to place a 17 mm valve in an adult patient. There are many well-known surgical procedures available to enlarge the annulus that could have been considered.

   Regarding the size of the aortic root, during the March 19, 2005 call, Dr. Ennix indicated that he was certain an intraoperative TEE had been performed because they always do a TEE on these cases, although there was no documentation of this. He stated that neither he nor the particular anesthesiologist on the case were that expert in reading TEEs. He indicated that it is not the custom to have an official reading by a cardiologist before surgery is completed.

   During the same phone conference, Dr. Ennix indicated that he was able to place the #19 St. Jude Regent spacer, but not the valve. He then placed the #17 valve. He felt that this small woman, who already had 4-5 children and led a sedentary life style, would be fine with the #17. The NMA reviewer felt this was too small for a 37-year-old woman weighing 135 pounds. Dr. Ennix indicated that the

patient now has a valve gradient of 23 and effective orifice area (EOA) of 0.73, which while not the 0.85 they try to achieve, was not so bad that the valve would likely need replacement anytime soon. The NMA reviewer stated it was extremely rare to have to place such a small valve in an adult and that the gradient of 23 at rest could easily be 60-70 with exertion.

In his follow-up letter of March 21, 2005, Dr. Ennix provided a table from St. Jude showing that the EOA of a 17 HP St. Jude was identical to that of a 19 Standard St. Jude mechanical heart valve, and that this valve provided her an EOA of 0.73. He provided preop and postop echo reports showing the EF unchanged at >60%. He also provided several articles addressing the effect of prosthesis-patient mismatch on patient survival. Two studies showed no reduction in intermediate survival (7 years).[5, 6] However one study with a longer follow-up (mean 12 years), did show that mismatch patients had a valve-related mortality of 25% compared to 16% in patients without mismatch.[7]

In addition, St. Jude Medical, the valve manufacturer, states an EOA index of less than 0.85 cm^2/m^2 can have clinical effects of sudden death, LV outflow obstruction and persistent LV hypertrophy, decreased quality of life, higher incidence of late adverse complications and increased early and late mortality.[8]

In conclusion, it is extremely unusual to place a #17 valve in an adult patient. It is unlikely that she will have regression of her LVH. With better visualization, the surgeon would likely have been able to consider enlarging the aortic annulus, which would have allowed placement of a more appropriate sized valve.

5. **Seriously deficient operative note.** The operative note did not describe the patient's native valve, (e.g. was it bicuspid?) nor did it mention the over 50 units of blood products given during the procedure. Dr. Ennix briefly mentioned that a #19 valve was initially used, but no details were provided as to why he switched. The operation was on 1/28/2004; Dr. Ennix dictated the op note on 1/31/2004, well beyond the acceptable standard of 24 hours. He signed the note three months later on 5/4/2004. Also, the progress note on post-op day one stated that the patient was doing well, when in actuality she was in respiratory failure.

6. **No documentation in record of informed consent.** The record contained only a standard consent indicating the name of the procedure. There was no documented discussion of the additional risks or the newness of the planned minimally invasive procedure. However, Dr. Ennix provided a letter from the patient's family, excerpted below, that indicates that he did explain at least some of the additional risks. Nevertheless, the chart documentation remains deficient. Dr. Ennix provided a letter authored by the patient, in Spanish, dated February 23, 2005. Dr. Ennix provided another letter that was translated dated February 20, 2005 (sic). The translated letter states that Dr. Ennix:

> ...explained everything to me before and after surgery...carefully and with great patience explained to me and my family the risks involved

in the operation including a possible long operation and possible death. I knew that it may be a long operation and I knew that I may die.... However, Dr. Ennix explained to me the various ways of doing the operation, including a smaller incision. I agreed to the smaller incision, even though I understood that it might be more difficult for Dr. Ennix.

Five Cases of Technical Errors Followed by Death (Three Cases), Complications (One Case) or Possible Future Harm (One Case)

ABS-009 Technical Errors Requiring Conversion to On-pump Leading to Death

This 79-year-old Jehovah's Witness, who had a PCI of the RCA and circumflex 7 years earlier, presented with a four-month history of exertional chest pressure and an abnormal stress echo. An elective cath on 1/9/2002 revealed 3-vessel CAD and Hgb of 11.3 at the time. Dr. Ennix performed a CABGx2 on 1/10. The patient could not be extubated on 1/11, but was described as neurologically intact. On 1/12, she was described as having significant left hemiparesis, which proved to be secondary to a right parietal infarct. The patient remained ventilator dependent, developed worsening pulmonary and infectious problems, and renal dysfunction. She died on 2/19/2002.

Issues

1. **Unclear status: urgent vs. elective.** This patient had chronic, but increasingly symptomatic angina due to 3-vessel CAD. CABG was indicated, but age and Jehovah's Witness status did imply somewhat increased operative risk. The anesthesiologist's written note on 1/10/2002 at 1230 indicated "urgency of case precludes optimization with Epogen." This is hard to reconcile with the cardiologist's note that stated, "She is admitted for elective cath." There was no compelling documentation that the operation had to be done urgently.

   During the March 26, 2005 phone conference, Dr. Ennix addressed this issue stating that this cardiologist had had a fair amount of experience with Jehovah's Witness patients and had followed this patient for over a decade. Given that EPO can take a month or more to become effective and because of the change in symptoms in the last month, the cardiologist felt that they needed to go ahead with surgery.

2. **Prolonged interval of cardiovascular compromise while converting from OPCAB to on-pump leading to death.** The patient had 3-vessel CAD with LVEF of 38%, an ACC/AHA Class I indication for surgery. Dr. Ennix had planned to do an OPCAB, but during surgery, converted to on-pump because of instability when positioning the heart. The anesthesia notes indicated hemodynamic compromise at 1530 and the patient on cardiopulmonary bypass about 1610.

   This prolonged period of ischemia was at least partially to blame for the patient's subsequent problems. While theoretically, off-pump technique might offer an advantage for a Jehovah's Witness who is anemic (since it avoids the

hemodilution of cardiopulmonary bypass), this theoretic advantage can only be realized if the surgeon can rely on not needing to convert emergently to on-pump technique. Thirty-eight minutes was a long time to achieve that conversion and relieve ongoing ischemic cardiac dysfunction. The intraoperative ischemia and subsequent need for increased fluids needed to maintain her BP likely initiated the cascade of events that began with the inability to wean from her from the ventilator on POD 1 and ended with her death one month later.

In the phone conference on March 26, 2005, Dr. Ennix was asked why the conversion took approximately 40 minutes. He stated that from the op note, he did not see why it took 40 minutes and he could only speculate. He stated that at times, the instability is only transient and if you wait 5-10 minutes and reposition, you can get over the problem. He indicated he chose to do the case off-pump because he felt he could better control blood loss.

3. **Postoperative right parietal infarct.** Based on the physician and nursing notes, the patient was neurologically intact until POD 2. That makes it unlikely that the patient's anemia caused the stroke. The CT scan showed a single right parietal infarct, suggesting an embolic rather than watershed infarct. The risk of perioperative stroke is clearly greater with increasing age, and the most common source of emboli in this age group is probably the ascending aorta. The CVA did not appear related to any specific quality of care issue, nor did there appear to be any specific action that could/should have prevented it.

   In the phone conference on March 26, 2005, when asked why it was not possible to wean the patient on the day of or the day following surgery, Dr. Ennix responded that perhaps she had already had some cerebral injury and she may have been fluid overloaded.

4. **Substandard documentation.** There was no detailed documentation of discussion with the patient regarding indications or operative risks. Based on the excerpts from the patient's daughter shown below, it does appear that Dr. Ennix explained the additional risks to the patient, but did not document this in the record. In addition, the op note did not describe the prolonged period of ischemia while converting to on-pump. Dr. Ennix provided a letter authored by the daughter of the patient dated February 18, 2005. The letter states:

   > At the time, Dr. Ennix explained to my mother the risks including death and alternatives. She and all of us understood the gravity of the situation and the risks very well, in particularly without the benefit of blood transfusions and wished to proceed with the surgery.

ABS-003 TECHNICAL ERRORS IN MINIMALLY INVASIVE AVR SURGERY LEADING TO COMPLICATIONS AND DEATH

This 76-year-old man presented with shortness of breath, fatigue and ankle swelling. A cardiac cath and echo revealed critical aortic stenosis and normal coronary arteries. Dr.

Ennix performed AVR with a minimally invasive incision on 1/30/2004; surgery lasted over six hours. Post-operatively the patient was lethargic, required re-intubation on 2/6 and died on 2/11/2004.

Issues

1. **Prolonged surgery time.** The 6-hour 18-minute surgery time was excessive. In total, the patient was in the OR for 10 hours 45 minutes. The substandard op note (see below) did not contain sufficient information to allow the reader to understand what caused the case to be prolonged. The most likely explanation was that the surgeon did not have adequate visual exposure through the minimally invasive incision.

2. **Intraoperative complications.** There was significant bleeding during the procedure with the patient receiving 6 units of PRBCs plus albumin and FFP. Given the subsequent severe AI, surgery was likely prolonged due to difficulty with visualization and placement of the aortic prosthesis.

3. **Failure to obtain post-op TEE.** As stated above, surgery was likely prolonged due to difficulty with visualization and placement of the aortic prosthesis. After this complicated surgery was complete, it would have been prudent and well within the standard of care to request that a TEE be performed, since it likely would have detected any abnormalities with the valve.

4. **Postop diminished CNS function and possible CVA.** The patient's level of consciousness fluctuated during the postop period. By 2/3/2004 he was noted to be lethargic and poorly responsive. A CT on that date showed a low-density mid-brain lesion thought to possibly represent a recent ischemic event. The prolonged bypass time and long operation time increased the predisposition to cerebral ischemia.

5. **Death due to complications.** The patient died from sudden cardiopulmonary arrest on 2/11/2004. The cardiologist's note the day prior noted severe AI. The AI was likely due to a technical difficulty in placing the prosthesis during the very long operation. The chances of the patient's eventual death would have been substantially less if the bypass time had been 1.5 to 2 hours. In his op note, Dr. Ennix described nothing that would appear to make the case complicated or explain the prolonged OR time.

   During the March 19, 2005 phone conference, Dr. Ennix indicated he wished he had documented why it took so long. He indicated a number of issues such as placement of lines and thin aorta; he thought he had bleeding under control, but had to go back repeatedly to control bleeding of the aorta. He stated he did not consider struggling with a suture line a complication or something sufficiently important that it needed to be outlined in the record; but he can see the other point of view.

On the call, Dr. Ennix stated that the regurgitation in this valve was a manufacturing issue because he examined the valve in postmortem, and it was clear that one leaflet was not in apposition. He talked to Medtronic/Mosaic Company and reported that a certain number of these valves will have regurgitation, as was reported to FDA. The report from the postmortem exam performed 2/12/2004 states: "One of the leaflets does not perfectly appose the other leaflets, leaving an approximately 4 x 1 mm gap." The autopsy exam of the heart showed "evidence of acute infarction (probably in the range of 4 to 24 hours)."

During the March 19, 2005 call, when asked if, in retrospect, there was anything he would have done differently, Dr. Ennix replied he takes great precautions in these patients and that he did not think there was anything he would have altered.

In conclusion, it is clear that this patient developed severe AI postoperatively, and that at postmortem, the valve was found to be damaged. What is unknown is whether the valve had a manufacturing defect, or whether it was damaged during implantation. The leaflets of the Mosaic valve are malleable and delicate. Given the excessive length of the surgery (6 hours, 18 minutes), there were likely technical difficulties that were not described in the op note. The type of damage described in the pathology report could have occurred from bending or distorting the sewing ring (normally a circle) during valve insertion. Inserting a sewing ring that is too large for the annulus can cause the ring of the valve to bend and not be a perfect circle, thus distorting the prosthetic ring so that the leaflets fail to appose properly, resulting in aortic insufficiency.

It is unknown whether the valve became defective during insertion or manufacture. If during insertion, the damage likely occurred due to poor exposure from the minimally invasive approach. If it resulted from a manufacturing defect, an extremely rare occurrence, this should have been detected by the surgeon upon valve inspection during insertion. In either case, a post op TEE should have been performed because it likely would have detected the abnormality prior to the patient leaving the OR, and it could have been corrected at that time. In this case, a series of technical and judgment errors led to bleeding, prolonged OR time, AI and death. All were preventable.

6. **Substandard op note.** The op note mentioned neither the bleeding nor the prolonged OR time. Despite being in the OR for almost 11 hours, the op note reads like a routine three-hour procedure. Neither the op note nor the echo report mentioned the enlarged ascending aorta.

ABS-006 UNPLANNED CONVERSION TO ON-PUMP CABG AND TECHNICAL ERRORS FOLLOWED BY COMPLICATIONS AND DEATH

This 87-year-old man with chronic angina was admitted to another hospital on 1/15/2004 with increasing pain, with a reported ECG suggesting inferior MI of unknown age and a Troponin of 1.7. He was transferred to Alta Bates Summit Medical Center on 1/16/2004

for a coronary angiogram that revealed a tight left main, tight LAD and circumflex lesions with chronically occluded RCA. A cardiac surgery consultation was requested and Dr. Ennix took the patient for emergent/urgent CABGx3 about five hours later. He started the case as on OPCAB, but later converted to on-pump. The patient's postop course was complicated by respiratory insufficiency, renal dysfunction, and sepsis. He died of sepsis on 2/11/2004.

Issues

1. **Need to convert from OPCAB to on-pump.** Dr. Ennix started the case as an off-pump coronary artery bypass, but after completing the first distal anastomosis, the patient became unstable and Dr. Ennix had to convert to on-pump.

   It is difficult to make a blanket statement as to whether the risks for this patient would have been lower with an on-pump procedure. Advocates of off-pump techniques would not consider left main disease, patient age or his ejection fraction to contraindicate an off-pump approach. However, the need to convert from OPCAB to on-pump is associated with significantly increased morbidity and mortality: an approximate 8-fold increase in mortality and a 5- to 7-fold increase in serious adverse outcomes, such as the renal and respiratory complications seen in this case.[9] This 87-year-old man received none of the benefits of OPCAB, but all the disadvantages associated with conversion.

   During the phone conference of March 26, 2005, when Dr. Ennix was asked to comment on the conversion, he stated he had a wealth of experience with beating hearts and that his conversion rate is relatively low, having had only 2-3 for the entire year.

2. **Need to redo a cardiac graft.** The perfusion note indicated that Dr. Ennix had to redo one bypass; this was not acknowledged in the operative note by the surgeon. The need to redo a graft after discontinuing cardiopulmonary bypass can happen to any surgeon, but rarely.

   During the phone conference of March 26, 2005, when Dr. Ennix was asked to comment on why the op note did not include redo graft and whether or not he went back on bypass, he replied, "That takes my totally by surprise." He stated that he did not remember redoing a graft, and could not imagine having to redo a graft and not including it in the op note. He said, however, he could imagine fixing a bleeder and not including it in the note because it is so routine.

   In his March 28, 2005 letter, Dr. Ennix stated that upon reviewing the perfusion and anesthesia records, "it is clear that I did not redo a graft." He went on to state that given the time frame of 65 minutes shown in the record, that this was insufficient for him to have gone back on bypass and then redone a graft. He felt it was more likely that he went back and "put a stitch or two in one of these anastomoses."

   Given that there was a 7-day delay until Dr. Ennix dictated the op note, it is

impossible to know with certainty what actually transpired. However, the perfusionist's note indicating the redo graft was written contemporaneously with the surgery, and Dr. Ennix certainly could have redone the graft off-pump in the 65-minute timeframe.

3. **Death following complications.** The patient left the OR in "good condition," but his postop course included respiratory, renal, and infectious complications. He died of sepsis on 2/11/2004. While the need to convert from off- to on-pump clearly increased the likelihood of death in this patient, there is not a clear causal link.

4. **Substandard documentation.** The surgeon's note failed to indicate that one bypass graft was redone. This is discussed in # 3 above.

Dr. Ennix's discussion of the surgical risks was very general in his typed consultation. Given the high risk of this patient, a more detailed discussion would have been appropriate. From the letter excerpted below, it appears that Dr. Ennix did discuss the risks and benefits of surgery with the patient and family, but failed to document this discussion in the record. Furthermore, during the phone conference of March 26, 2005, Dr. Ennix indicated that this was a Mid-Eastern family, several of whom did not speak English very well, and that he had spent a very long time explaining things to them. He indicated that he now definitely understands the needs to spend more time with his documentation: "I have learned my lesson in that regard." Dr. Ennix provided a letter authored by a relative of the patient (nature of relationship not known) dated February 18, 2005. The letter states:

> He explained all of the risks, benefits before surgery and we, of course, understood that there were risks involved, especially at [the patient's] age....All of us appreciated the time that Dr. Ennix spent with us and [the patient] explaining things before and after the surgery.

ABS-001 TECHNICAL ERRORS IN MINIMALLY INVASIVE SURGERY LEADING TO VENTRICULAR DAMAGE AND SECOND SURGERY

This 39-year-old man with aortic insufficiency underwent a minimally invasive AVR on 1/28/2004. Surgery started at 0914 and concluded at 1645. He developed severe AS/AI immediately post-op and underwent aortic valve re-replacement on 1/31/2004 (full sternotomy lasting 4½ hours). He was discharged on 2/17/2004 in stable condition.

Issues

1. **Questionably informed consent.** The patient was a severe schizophrenic and there was no evidence of fully informed consent. A pre-op psychiatric consult in the chart would have satisfied the informed consent requirement.

Dr. Ennix provided a letter authored by the patient dated February 18, 2005. The letter states:

> He drew pictures and he showed me a model heart so that I would understand. In addition, I also understood that he would try to do the operation through a small incision. I understood this and I agreed. I knew that the operation carried some risks including death and bleeding.

Regarding the second operation and length of the first operation, the patient states:

> ...the cardiologist and Dr. Ennix told me that the new valve needed to be replaced because it wasn't working well.... I understood that I needed the second operation and I agreed to it... understood that the first operation might need to be longer because of the small incision.

During the March 19, 2005 phone conference, Dr. Ennix indicated he had had a preoperative discussion with the patient and his representative from board and care. It was Dr. Ennix's impression that he fully understood what was to come about. Dr. Ennix acknowledged that perhaps it would have been a good idea to have a psych evaluation beforehand.

2. **Technical error related to minimally invasive approach leading to ventricular damage and need for second surgery.** The operative note was not sufficiently detailed to understand exactly what went wrong (see below), but there was definitely a technical error, most likely related to the minimally invasive approach. Following the first surgery, left ventricular function was worse, indicating inadequate myocardial protection during surgery.

   During the March 19, 2005 phone conference, Dr. Ennix was asked what caused the severe, but highly unusual, combined AI and AS on the first postop day. He indicated that AI/AS was the interpretation of the echo-reading cardiologist. His own impression was that the patient had primarily AI. He could not imagine why the patient might have AS. Perhaps, he explained, if the prosthesis was unstable, it might give the appearance of AS on echo.

   He stated he thought his visualization was good, but the valve was a tight fit per the op report. He thought there was a problem with seating of this valve, an unusual situation for him. There was probably a perivalvular leak that tilted the valve, which led to obstruction, but he could not identify it at the table, and he did not recall the TEE showing a problem with the valve before leaving the OR. (TEE was not mentioned in chart.) Therefore, he replaced the valve with a different model, Edwards, at the second surgery.

   During that call, Dr. Ennix was also asked what he thought caused the

deterioration in the left ventricular function during surgery. He indicated that they protect these patients well, use blood cardioplegia and use enriched blood CP at the end of the case, as documented in the perfusion record. By time of discharge, he indicated the patient was doing well, and continues to do well. But, Dr. Ennix said, there was a problem with LV protection.

In a followup letter dated March 21, 2005, Dr. Ennix stated that although the postoperative echo suggested left ventricular impairment with an ejection fraction of 40-45%, the "most recent echocardiogram shows full recovery and that this initial impairment represented only a 'stunned' myocardium. The current ejection fraction is 71%." The echo report also indicated that the patient had a relatively small valve area of 1.1.

In conclusion, Dr. Ennix made technical errors that led to ventricular damage and a perivalvular leak—and the need for a second surgery. The leak should have been apparent in the OR, and the patient should not have left the OR without it being detected and repaired. Fortunately, the patient recovered his LV function, notwithstanding the technical errors by Dr. Ennix.

3. **Failure to obtain TEE in OR.** Dr. Ennix should have obtained a TEE before leaving the OR, which would have elucidated the problem and most likely avoided the need for a second operation.

   During the March 19, 2005 phone conference, Dr. Ennix stated they routinely obtain TEEs on all these patients at the end of surgery, although it was not mentioned in the chart in this case. He was confident that the anesthesiologist who read it reads TEEs well.

4. **Prosthetic valvular dysfunction.** The second operation was needed because the patient had a documented postop prosthetic dysfunction and a para-valvular leak. It was likely that the surgeon had poor visualization. Given the findings of critical AS and AI immediately post op (perivalvular leak), it may be that the surgeon did not place the sutures properly, so that the valve was tilted, thereby obstructing the outflow.

   In a followup letter dated March 21, 2005, Dr. Ennix stated that he agreed that the "problem probably resulted from a perivalvular aortic insufficiency...."

5. **Substandard documentation.** Both the operative note from the 1/29/2004 and 1/31/2004 surgeries were dictated on 1/31/2004, so that the note from the first surgery was out of conformance with both good medical practice and JCAHO standards. In the op note from the second surgery (1/31/2004), there was no description of the preop findings or the problems which the operation was undertaken to correct. The patient had a #27 valve and they replaced it with a #25 valve despite the larger valve being described as stenotic. Furthermore, the operative note in this case had numerous transcription errors, indicating that it was not reviewed by the surgeon and corrected.

[redacted] Medical Audit
[redacted] HR Consulting

ADDENDUM June 30, 2005, to

Focused Review of Medical Records of Coyness L. Ennix, Jr., MD, Dated May 3, 2005

ABS-004 Prolonged Surgery with Possible Future Harm (Page 27)

Issues

2. **Prolonged OR time.** The op note described a routine procedure, which is contrary to the observed surgical time of 7 hours 24 minutes (total time in OR of almost 12 hours). A routine mitral valve replacement generally takes around three hours.

During the March 19, 2005 phone conference, when questioned about the absence of a preop echo (except for one in 2001 showing AI), Dr. Ennix replied he was confident the patient had a preop echo, but could not tell the date.

ABS-004 PROLONGED SURGERY WITH POSSIBLE FUTURE HARM

This 75-year-old man with severe mitral regurgitation was admitted for elective mitral valve replacement surgery. The H&P stated that the patient was diagnosed several years ago and was being followed with serial echocardiograms. The patient was admitted denying chest pain, shortness of breath, paroxysmal nocturnal dyspnea or orthopnea, and works out daily, walking up to 45 minutes and lifting weights. Preop echo was reported to show severe mitral regurgitation. The cardiac cath report indicated severe mitral regurgitation, but no significant coronary artery disease. Dr. Ennix performed a minimally invasive mitral valve replacement with a 29 mm valve on 2/05/04 and the patient was discharged home on 2/13/04.

Issues

1. **No documentation of indications.** There was no preoperative treadmill evaluation to document LV function under stress. This is important; if the patient can exercise to Stage 4 of a Bruce Protocol, then surgery may be safely postponed.

2. **Prolonged OR time.** The op note described a routine procedure, which is contrary to the observed surgical time exceeding 12 hours (total time in OR almost 20 hours). A routine mitral valve replacement generally takes around three hours.

   During the March 19, 2005 phone conference, when asked about the reading of the TEE in this case, Dr. Ennix replied that cardiac surgeons are not experts at TEE even though they read them. Cardiologists need to read them, he said.

   Regarding the prolonged op time, Dr. Ennix replied that with these minimally invasive cases and early experience, that the op time was prolonged. He indicated that as the team (technicians, nurses, anesthesiologists, perfusionists) becomes more familiar with them that times will go down. Dr. Ennix also said that what is important is deliberate and excellent myocardial protection.

   During the prolonged surgery the patient received large amounts of blood products (4 units of PRBCs, 4 units of FFP, 2 units of platelets and 10 units of cryoprecipitate), which may be associated with future harm.

3. **Substandard op note.** The op note was excessively brief, omitting operative time and blood usage. While the blood usage may have been indicated, the indication was not documented in the surgical notes.

   During the March 19, 2005 phone conference, Dr. Ennix was asked about the

incomplete op note. The surgery was started at 0930 and finished at 1930, but there is no documentation of what happened. The patient left the OR on milrinone, epinephrine and norepinephrine—but none of this was documented.

Dr. Ennix indicated that it is absolutely clear to him that he would not be in this trouble had he documented better, "I've learned my lesson." He stated he will do more extensive documentation starting now.

In addition, there is no indication in the written or dictated record that informed consent was obtained. Dr. Ennix provided a letter written by the patient stating that in Dr. Ennix's office:

> He took an extraordinary amount of time explaining to us the facets of the mitral valve operation, the pathology of the valve, and why I needed the operation.... I understood the smaller incision would be more technically demanding and would perhaps take longer.... He explained...the risks including bleeding, stroke and death.... Both my wife and I think the world of Dr. Ennix.

During the March 19, 2005 phone conference, Dr. Ennix indicated he had spent 30-40 minutes explaining the operation and had given the patient/family his home and cell phone numbers, in case they had questions. In the hospital, he went over risks again, with the resident present. The resident dictated the H&P, but failed to mention this discussion. He agreed that this was clearly his responsibility and apologized. He added that there is no question in his mind that there was informed consent, but the resident failed to document it.

Delay in Dictating/Signing Operative Notes

A summary of the dates of surgery and operative note dictation is shown in the table below. Dr. Ennix performed 13 surgeries, including 4 valve replacements/repairs, 1 valve redo, 6 CABGs, 1 tracheostomy and 1 exploration. Only 5 of the 13 operative notes were dictated in a manner consistent with the Medical Staff Rules & Regulations (provided by Dr. Ennix), which specify: "All Operative Reports must be dictated immediately following surgery..." On average, he completed his dictation 1.5 days post surgery, with a range of 0-7 days, and he signed his op notes 80 days post dictation, with a range of 5-300+ days. The standard of care is to dictate the note within 24 hours and sign it promptly, but certainly within two weeks.

[illegible]	Type of Surgery	[illegible]	[illegible]	[illegible]
ABS-001	AVR Redo AVR	1/29/2004 1/31/2004	2 0	94 94
ABS-002	AVR	1/28/2004	3	94
ABS-003	AVR	1/30/2004	1	95
ABS-004	MVR	2/5/2004	4	300*
ABS-005	CABG	2/29/2004	0	65
ABS-006	CABG	1/16/2004	7	102
ABS-007	CABG	7/23/2004	1	6
ABS-008	CABG	5/7/2004	0	84
ABS-009	CABG Tracheostomy	1/12/2002 1/27/2002	0 0	54 39
ABS-010	CABG Exploration	10/15/2004 10/15/2004	1 1	5 5
Average			1.5 Days	80 Days

*One case remained unsigned at 300 days.

Conclusions

NMA reviewed nine cases from January 16, 2004 to October 11, 2004 and one case from January 9, 2002 where Coyness L. Ennix, Jr., MD performed cardiac surgery. Peer review at the hospital had identified problems in all of the cases, which were then sent to NMA for outside review. Four of the cases involved minimally invasive valve surgery and six involved CABG surgery, three of which were initially planned as off-pump procedures. Six patients died; one other arrested, was placed on ECMO and transferred to another hospital for salvage LVAD.

In addition to reviewing the records of these 10 cases, NMA reviewed written correspondence from Dr. Ennix and held two phone conferences with him (March 19, 2005 and March 26, 2005) to obtain further clarification of events.

During the March 19, 2005 and March 26, 2005 phone conferences, Dr. Ennix was respectful and illustrated a willingness to carefully consider the opinions of the reviewers. In addition, he indicated that he would improve his documentation and other practices. During both calls, there was a discussion of the interplay between cardiologist and cardiac surgeon and the point was made that when Dr. Ennix believes the surgical risk is too high, he needs to be prepared to state this unequivocally.

The conclusions of this report are based on the documentation as stated in the medical record, as well as supplemental information provided by the hospital and Dr. Ennix. This review identified three major problems with the care delivered by Dr. Ennix: poor judgment, poor technique and substandard documentation.

Poor Judgment

The review identified five cases of poor judgment [ABS-002, 005, 007, 008, 010]. This lead to death in three cases [ABS-005, 007, 008], arrest/ECMO in one [ABS-010] and severe complications in another [ABS-002]. In the cases reviewed, Dr. Ennix used poor judgment in deciding whether to operate, when to operate, the best option for the patient, and when additional information should have been obtained before making the decision. He operates on very sick patients with complex problems; these patients deserve a thoughtful and iterative decision-making process that was often lacking in the cases reviewed. Many of these patients had rapidly changing clinical circumstances, with indications and contraindications varying over a period of hours or days. The cases reviewed illustrate that Dr. Ennix frequently failed to integrate his patients' changing clinical situation into his decision making.

Poor Technique

The review also identified six cases of substandard technique, (one of which [ABS-002] is presented in the Poor Judgment section) [ABS-001, 002, 003, 004, 006, 009]. Dr. Ennix had technical difficulty in all four valve cases reviewed, all of which were begun as minimally invasive procedures, resulting in death in one case [ABS-003] and severe complications in three others [ABS-001, 002, 004]. There were three other cases

reviewed where Dr. Ennix initially planned off-pump CABG procedures. All three of these required the patient being placed on-pump, and were associated with intraoperative errors (judgment or technical) that were followed by cardiac arrest or death [ABS-006, 009, 010].

Each of these seven cases with intraoperative judgment or technical errors [ABS-001, 002, 003, 004, 006, 009, 010] was started as either minimally invasive valve surgery or planned as off-pump CABG surgery. From the information supplied by the hospital, the cases reviewed here were among the very first minimally invasive valve cases performed at the hospital and by Dr. Ennix. Minimally invasive surgery has a steep learning curve. When embarking on new types of surgery, it is important to begin with low risk cases.

One of the three planned OPCABs that converted to on-pump had a prolonged conversion time [ABS-009]. Until OPCAB cases become routine, it is best to have the bypass pump setup in the room and primed. If cases are going well, it is then reasonable to have it setup, but unprimed; and later not setup at all. Judging by the prolonged conversion time to bypass in this case, the pump was neither setup nor primed.

While there are many advocates of OPCAB who would argue its superior results, about three-quarters of all US CABGs are still performed on-pump. In addition, the mortality risk of emergency conversion to on-pump is 8-fold higher.[9] In this sample of cases, patients often incurred the risks of "more limited surgery" without receiving the corresponding benefits.

Substandard Documentation

Finally, Dr. Ennix's operative notes were grossly substandard. His notes do not provide detail of operative findings or describe what actually happened in the operating room. Rather, his notes convey the impression that surgery was routine, when in fact, there were multiple complications and very prolonged surgery times. While the records did not contain documentation of truly informed consent, Dr. Ennix provided numerous letters from his patients or their families indicating that he had in fact informed them, in depth, about risks and benefits. With respect to the minimally invasive surgery procedures, the discussion regarding consent did not indicate that patients were informed that this type of procedure was new to the hospital. Regarding the timeliness of dictating and signing operation notes for the 13 procedures reviewed here, on average, Dr. Ennix dictated his operative notes 1.5 days post surgery and signed them 80 days post dictation.

Conclusion

In conclusion, this review of cases, pre-selected because of known problems, identified three major problems with the care delivered by Dr. Ennix: poor judgment, poor technique with minimally invasive valve and off-pump CABG procedures and grossly substandard documentation. If these patterns of care go uncorrected, it is likely that there will be future patient harm.

Systems Issues

In addition to issues regarding Dr. Ennix, discussed above, the review identified a number of systems issues that are addressed in this section. Since the purpose and scope of this review was to evaluate care provided by Dr. Ennix and only encompassed 10 cases but no on-site observations, there may be additional systems issues not addressed in this report. The system issues presented here are intended to aid the medical staff and hospital in better understanding some of the issues relating to the deaths and complications observed in the review of these cases; they are not meant to exonerate acts of individual physicians.

The best cardiac surgery units exhibit an integrated team approach with surgeon, cardiologist, anesthesiologist, pump technician, nurses and post surgery personnel organized and operating in a closely coordinated manner. The cases reviewed here do not show such close coordination. Examples include times when the cardiologist did not perform a thorough evaluation, omitting a cardiac cath or right heart cath, or providing an incomplete report of echo findings; lack of a coordinated plan between the cardiologist and cardiac surgeon; delays in getting OPCAB patients onto bypass when the need arose; and making decisions based on TEE interpretations made by less than fully qualified individuals.

Specific examples include:

1. **Poor coordination among members of the cardiac surgery team** during both the evaluation and decision-making phase of care.

   This was seen in ABS-005 and 008 regarding the decision whether to perform CABG or PCI. In both cases, PCI was a much lower risk option, yet there was no evidence that this possibility was seriously considered. In ABS-007, the poor communication among the cardiologist, CV surgeon, vascular surgeon and anesthesiologist, regarding the sequence of carotid and coronary surgery, played a major role in this patient's ultimate death. Similarly in ABS-010, poor communication between the cardiologist and CV surgeon led to the delay in surgery, and likely played a role in the patient's arrest and need for ECMO/LVAD.

2. **Need for qualified individuals to read and record findings from TEEs.** The absence of a TEE or correctly interpreted TEE directly led to the need for a second surgery in case ABS-001. In ABS-003, and perhaps ABS-004, the lack of a TEE or a correctly interpreted TEE played a role in this patient's death. A TEE would have likely detected any abnormalities with the patient's valve before the patient left the OR.

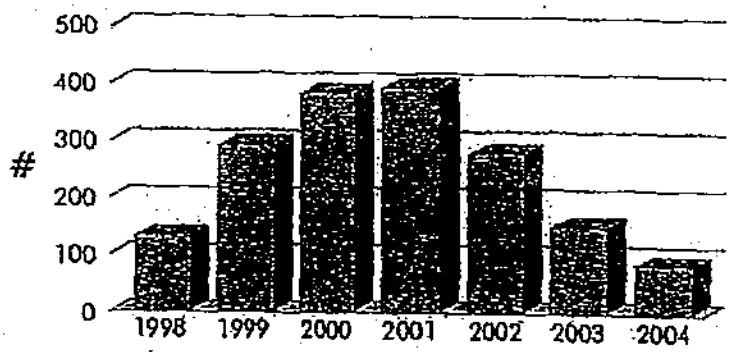
   Many top cardiac surgery centers have a systematic arrangement for performing TEEs. TEEs are standard practice protocol in all valve repairs and in some centers, in valve replacements as well. Often hospitals will have a rotation of qualified cardiologists assigned to the surgery suite, who are responsible for

performing, interpreting and documenting TEE findings. This approach benefits the patient, surgeon and hospital.

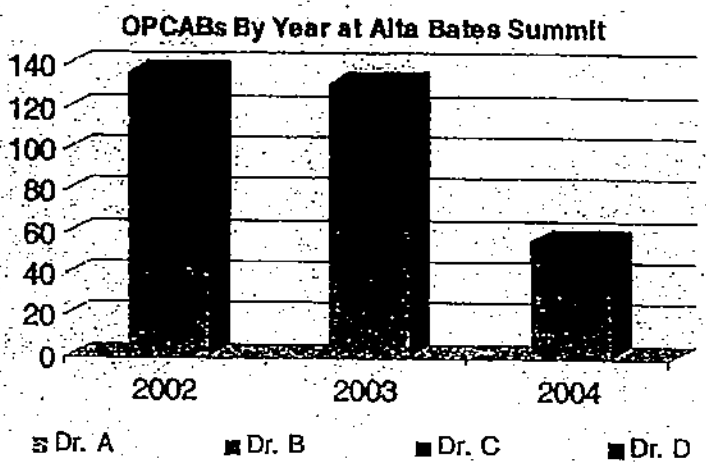
3. **Need to assess risks/benefits of less invasive surgery for each individual patient.**

There is a definite learning curve to performing less invasive cardiac surgery. While the hospital has been performing OPCABs for a number of years now, the issue of when to have the perfusionist setup the pump must be evaluated on a case-by-case basis, taking into account both the risk level of the patient and the experience of the surgeon.

In the US today, many physicians are proponents of minimally invasive and OPCAB procedures, yet not all surgeons have the training and experience to perform these new procedures with the same expertise with which they perform their standard counterparts. In addition, time does not always bear out all the early advantages of these procedures. For example, recent data demonstrate that the safety of on-pump and off-pump surgery is equivalent. This is demonstrated by the recently declining OPCAB volume at the Cleveland Clinic, one of the pioneers in OPCAB. They have performed a steadily decreasing number of OPCAB cases over the past few years, declining in stepwise fashion from almost 400 in 2001 to under 100 in 2004, at a time when their overall cardiac surgery volume was increasing (see chart below).[10]



At Alta Bates Summit Medical Center, the number of OPCABs performed decreased dramatically in 2004. As shown in the graph below, there were approximally 135 OPCABs performed in 2002 and 2003. However, only 57 were performed in 2004. While we do not know if this trend will continue in 2005, a minimum number of OPCABs need to be performed to maintain the skills of the surgeon and the team (technicians, nurses, anesthesiologists, perfusionists, etc.).



Similarly, minimally invasive valve surgery is a new procedure at Alta Bates Summit Medical Center. In reviewing three of the early cases here, it became clear that there was not a fully-integrated team approach in place.

While striving to reduce pain and complications is an important goal, the risks and benefits to the patient must be evaluated individually for each surgeon and institution. There are available processes to minimize the pressure on a surgeon to perform a procedure that happens to be preferred by a referring physician.

4. Similarly, there are no procedures in place to resolve the best treatment option in high-risk cases. As discussed above, there were a number of cases where the reviewers felt that PCI would have been a better and safer option than the cardiac surgery performed. This is a common problem in the US today. To address this issue, many hospitals have found it advantageous to bring another surgeon, and when warranted, another interventional cardiologist, into the decision-making process, which has resulted in improved patient safety.

In conclusion, the reviews identified a number of system processes that could be enhanced in the cardiac surgery program, with the goal of improving outcomes. These include better coordination among team members pre-operatively, during the evaluation and decision-making phase, as well as during the actual surgical procedure; a more systematic approach to performing and reading TEEs; safer ways to introduce and monitor new procedures; and methods to protect the patient when peripheral pressures may force less than optimum decision making.

Appendix 1. Reviewer Qualifications

REVIEWER 004	
Specialty	Thoracic Surgery
Licensure	California
Board Certified	Surgery, Thoracic Surgery
Positions	Chief, Division of Cardiothoracic Surgery 2000-02 Member Medical Executive Committee 1995-present Clinical Associate Professor, Division of Cardiothoracic Surgery, University Medical Center 1975-99
Member	Committee on Coronary Artery Disease, American College of Chest Physicians Section on Cardiovascular Surgery, American College of Chest Surgeons Fellow - American College of Cardiology, Chest Surgeons Society of Thoracic Surgeons
Practice Status	Active
Publications	39

REVIEWER 084	
Specialty	Cardiovascular Surgery, Thoracic Surgery
Licensure	Illinois, North Carolina, Massachusetts
Board Certified	American Board of Surgery; American Board of Thoracic Surgery
Positions	Chief Section of Cardiac Surgery, major medical center; Assistant Professor of Surgery, major university medical center; Vice President, Medical Staff, major medical center.
Member	American Association for Thoracic Surgery, American Association for Vascular Surgery, American College of Cardiology, Society of Thoracic Surgeons, American College of Surgeons
Practice Status	Active
Publications/ Lectures	50+

REVIEWER 094	
Specialty	Cardiology
Licensure	Indiana
Board Certified	American Board of Internal Medicine, Subspecialty in cardiovascular diseases and interventional cardiology
Positions	Professor of Clinical Medicine (cardiology), Major University Hospital; Attending Cardiologist and Director of Cardiac Catheterization Lab and Interventional Cardiology, Major University Hospital
Member/ Committees	Fellow, American Heart Association, Council on Clinical Cardiology Fellow, American College of Cardiology, American College of Chest Physicians, American college of Physicians AHA – Committee of Cardiac Catheterization (1997-2000) Peripheral Vascular Disease Committee, ACC Abstract Grader, Scientific Sessions, AHA (2001-2003)
Practice Status	Active
Publications/ Lectures	100+

Appendix 2. Select Supplemental Information

NMA received various written correspondences from the hospital and Dr. Ennix. Below is a list of the letters received by NMA. Various literature and data were also included with each letter that is not listed.

1. Letter to Dr. Smithline from Drs. Paxton and Isenberg dated January 4, 2005.
2. Letter to Dr. Smithline from Dr. Ennix dated January 30, 2005.
3. Letter to Dr. Smithline from Dr. Ennix dated March 3, 2005.
4. Letter to Drs. Smithline and Housman from Dr. Ennix dated March 21, 2005.
5. Letter to Drs. Smithline and Breyer from Dr. Ennix dated March 28, 2005.
6. Letter to Drs. Smithline and Breyer from Dr. Ennix dated March 31, 2005.
7. Letter to Dr. Isenberg from Dr. Ennix dated April 5, 2005.

Appendix 3. Reviews

ABS-002	1282678	402700403	01/28/2004
ABS-004	1283240	403400672	02/05/2004
ABS-006	1281866	401501034	01/16/2004
ABS-008	527129	412700776	05/06/2004
ABS-010	1124908	428400252	10/11/2004

Appendix 4. References

[1] Akins CW, Moncure AC, Daggett WM et al. Safety and efficacy of concomitant carotid and coronary artery operations. Ann Thorac Surg. 1995;60:311-8.

[2] Takach TJ, Reul GJ, Cooley DA et al. Is an integrated approach warranted for concomitant carotid and coronary artery disease? Ann Thorac Surg. 1997;64:16-22.

[3] Rizzo RJ, Whittemore AD, Couper GS et al. Combined carotid and coronary revascularization: The preferred approach to the severe vasculopath. Ann Thorac Surg. 1992;54:1099-109.

[4] Darling III RC, Dylewski M, Chang BB et al. Combined carotid endarterectomy and coronary artery bypass grafting does not increase the risk of perioperative stroke. Cardiovascular Surgery. 1995;65.

[5] Hanayama N, Christakis GT, Mallidi HR et al. Patient prosthesis mismatch is rare after aortic valve replacement: Valve size may be irrelevant. Ann Thorac Surg 2002;73: 1822-9.

[6] He GW, Grunkemeir GL, Gately HL et al. Up to thirty-year survival after aortic valve replacement in the small aortic root. Ann Thorac Surg 1995;59:1056-62.

[7] Rao V, Jamieson WRE, Ivanov J et al. Prosthesis-patient mismatch affects survival after aortic valve replacement. Circulation. 2000;102 [Suppl III):III-5 – III-9.

[8] St. Jude Medical. Effective Orifice Area Index Calculator. Cited March 30, 2005. http://www.sjm.com/resources/patientprosthesismismatch.aspx?section=EOAICalculator

[9] Patel NC, Patel NU, Loulmet DF, McCabe JC and Subramanianb VA. Emergency conversion to cardiopulmonary bypass during attemped off-pump revascularization results in increased morbidity and mortality. J Thoracic and Cardiovasc Surgery. 2004;128:655-661.

[10] Surgical Thoracic and Cardiovascular Surgery: 2004 The Cleveland Clinic Foundation. Cited April 25, 2005.http://www.clevelandclinic.org/heartcenter/pub/about/surgoutcomes/coronary/coronary2.asp?firstCat=59&secondCat=440&thirdCat=444

APPENDIX B

Tabular STS Data as Provided to the Ad Hoc Committee by Dr. Ennix

Summ... Medical Center Open Heart Cases
STS Operative Mortalities: Predicted Risk vs. Observed
Dr. Ennix and Non-Kaiser Surgeons 1/1/1999 - 4/30/05

4

	1999					
	n	Deaths	Predicted Mortality	Mortality	95% CI Low	95% CI High
	24	2		8.3%	1.03%	27.0%
	17	2	2.7%	11.8%	1.46%	36.4%
Valve	2	0	9.6%	0.0%	0.00%	77.6%
Valve	0	0	n/a	0.0%	n/a	n/a
and Non-Kaiser MDs	267	12		4.5%	2.34%	7.7%
Other MDs	180	8	4.0%	4.4%	1.94%	8.6%
Valve Other MDs	38	0	3.7%	0.0%	0.00%	7.6%
Valve Other MDs	17	1	8.1%	9.0%	0.15%	28.7%
total	291	14		4.8%	2.66%	7.9%
	2000					
	n	Deaths	Predicted Mortality	Mortality	95% CI Low	95% CI High
	56	4		7.1%	1.98%	17.3%
only	47	1	3.1%	2.1%	0.05%	11.3%
ated Valve	4	0	2.2%	0.0%	0.00%	57.2%
B + Valve	1	1	29.7%	100.0%	5.00%	100.0%
n CE	297	8		2.7%	1.17%	5.2%
B only Other MDs	217	6	3.7%	2.8%	1.02%	5.9%
ated Valve Other MDs	26	1	4.7%	3.0%	0.10%	19.6%
B + Valve Other MDs	17	0	8.4%	0.0%	0.00%	16.2%
mmit total	353	12		3.4%	1.77%	5.9%
	2001					
	n	Deaths	Predicted Mortality	Mortality	95% CI Low	95% CI High
	51	3		5.9%	1.23%	16.2%
CB only	39	2	2.8%	5.1%	0.63%	17.3%
olated Valve	6	1	4.9%	16.7%	0.42%	64.1%
CB + Valve	3	0	3.5%	0.0%	0.00%	63.2%
on CE	238	11		4.6%	2.33%	8.2%
CB only Other MDs	152	6	4.0%	3.9%	1.46%	8.4%
olated Valve Other MDs	39	0	7.3%	0.0%	0.00%	7.4%
CB + Valve Other MDs	18	2	7.9%	10.5%	1.30%	33.1%
mmit total	289	14		4.8%	2.67%	8.0%
	2002					
	n	Deaths	Predicted Mortality	Mortality	95% CI Low	95% CI High
E	64	3		4.7%	0.98%	13.1%
CB only	46	2	2.4%	4.3%	0.53%	14.8%
olated Valve	6	0	3.8%	0.0%	0.00%	39.3%
CB + Valve	1	1	15.5%	100.0%	5.00%	100.0%
on CE and Non-Kaiser MDs	246	4		1.6%	0.44%	4.1%
CB only Other MDs	163	3	3.0%	1.8%	0.38%	5.3%
olated Valve Other MDs	30	0	6.2%	0.0%	0.00%	9.5%
CB + Valve Other MDs	18	0	7.9%	0.0%	0.00%	15.3%
mmit total	310	7		2.3%	0.91%	4.6%

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Su[illegible]t Medical Center Open Heart Cases
STS Operative Mortalities: Predicted Risk vs. Observed
Dr. Ennix and Non-Kaiser Surgeons 1/1/1999 - 4/30/05

	2003					
	n	Deaths	Predicted Mortality	Mortality	95% CI Low	95% CI High
CE	118	10		8.5%	4.14%	15.0%
ACB only	73	1	3.8%	1.4%	0.03%	7.4%
Isolated Valve	10	2	2.5%	20.0%	2.52%	55.6%
ACB + Valve	13	2	12.2%	15.4%	1.92%	45.4%
Non CE and Non-Kaiser MDs	224	12		5.4%	2.80%	9.2%
ACB only Other MDs	131	6	3.7%	4.6%	0.17%	9.7%
Isolated Valve Other MDs	31	2	4.6%	6.5%	0.79%	21.4%
ACB + Valve Other MDs	11	2	6.9%	18.2%	2.28%	51.8%
Summit total	342	22		6.4%	4.08%	9.6%
	2004					
	n	Deaths	Predicted Mortality	Mortality	95% CI Low	95% CI High
CE	97	9		9.3%	4.[illegible]0%	16.9%
ACB only	58	4	3.8%	6.9%	1.91%	16.7%
Isolated Valve	15	2	5.0%	13.3%	1.66%	40.5%
ACB + Valve	5	0	12.2%	0.0%	0.00%	45.1%
Non CE and Non-Kaiser MDs	244	10		4.1%	2.00%	7.4%
ACB only Other MDs	127	2	3.1%	1.6%	0.19%	5.6%
Isolated Valve Other MDs	38		*	0.0%	0.00%	7.6%
[illegible]B + Valve Other MDs	18		*	5.6%	0.14%	27.3%
[illegible]ummit total	341	19		5.6%	3.40%	8.6%
	2005					
	n	Deaths	Predicted Mortality	Mortality	95% CI Low	95% CI High
CE	21	1		4.8%	0.12%	23.8%
ACB only	15	1	6.9%	6.7%	0.17%	32.0%
Isolated Valve	2	0	2.4%	0.0%	0.00%	77.6%
ACB + Valve	1	0	1.1%	0.0%	0.00%	95.0%
Non CE and Non-Kaiser MDs	75	2		2.7%	0.32%	9.3%
ACB only Other MDs	38	1	3.2%	2.6%	0.07%	13.8%
Isolated Valve Other MDs	7	0	5.2%	0.0%	0.00%	34.8%
ACB + Valve Other MDs	3	0	6.1%	0.0%	0.00%	63.2%
Summit total	96	3		3.1%	0.65%	8.9%

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Sa[illegible]ait Medical Center Open Heart Cases
STS Operative Mortalities: Predicted Risk vs. Observed
Dr. Ennix and Non-Kaiser Surgeons 1/1/1999 - 4/30/05

	1999 through April 2005 total					
	n**	Deaths	Predicted Mortality	Mortality	95% CI Low	95% CI High
[illegible]						
	431	32		7.4%	5.13%	10.3%
ACB only	295	13	3.3%	4.4%	2.40%	7.4%
Isolated Valve	45	5	3.8%	11.1%	3.71%	24.1%
ACB + Valve	24	4	10.7%	16.7%	4.75%	37.4%
Non CE and Non-Kaiser MDs	1591	59		3.8%	2.90%	4.8%
ACB only Other MDs	1008	31	3.6%*	3.1%	2.21%	4.3%
Isolated Valve Other MDs	207	3	5.4%*	1.5%	0.30%	4.2%
ACB + Valve Other MDs	103	6	8.0%*	5.8%	2.17%	12.3%
Summit total	2022	91		4.5%	3.64%	5.5%

* Weighted average of relevant predictions weighted by number of patients to which predictions applied